"A PROSPECTIVE OBSERVATIONAL STUDY ON THE TREATMENT OF PRESTERNAL KELOIDS BY EXCISION AND RECONSTRUCTION"

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The faculty of

ALL INDIA INSTITUTE OF MEDICAL SCIENCES, BHOPAL

For the award of the degree of M.Ch. in the subject of

PLASTIC AND RECONSTRUCTIVE SURGERY

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ALL INDIA INSTITUTE OF MEDICAL SCIENCES, BHOPAL

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AIIMS, Bhopal Institutional Human Ethics Committee- Student Research (IHEC-SR), in its 7th meeting held on 22nd February 2023, discussed your proposal titled "A Prospective Observational Study on the Treatment of Presternal Keloids by Excision and Reconstruction" and evaluated it for suitability for your dissertation as required for the fulfillment of DM/M.Ch program.

The following members attended the meeting:

1. Prof. D. K. Pal, Former HoD Community Medicine, GMC, Bhopal…… ...Chairperson
2. Prof. Rajnish Joshi, Professor of General Medicine, AIIMS, Bhopal…..…….. Member
3. Prof. Amit Agrawal, Professor of Neurosurgery, AIIMS, Bhopal…….. Member
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The AIIMS, Bhopal IHEC-SR approves your research protocol. All research-related activities must begin only after the date of this approval. The validity of this approval is two years from the date of issuance. Please submit a closure report/renewal request before the expiration of the validity for this approval.

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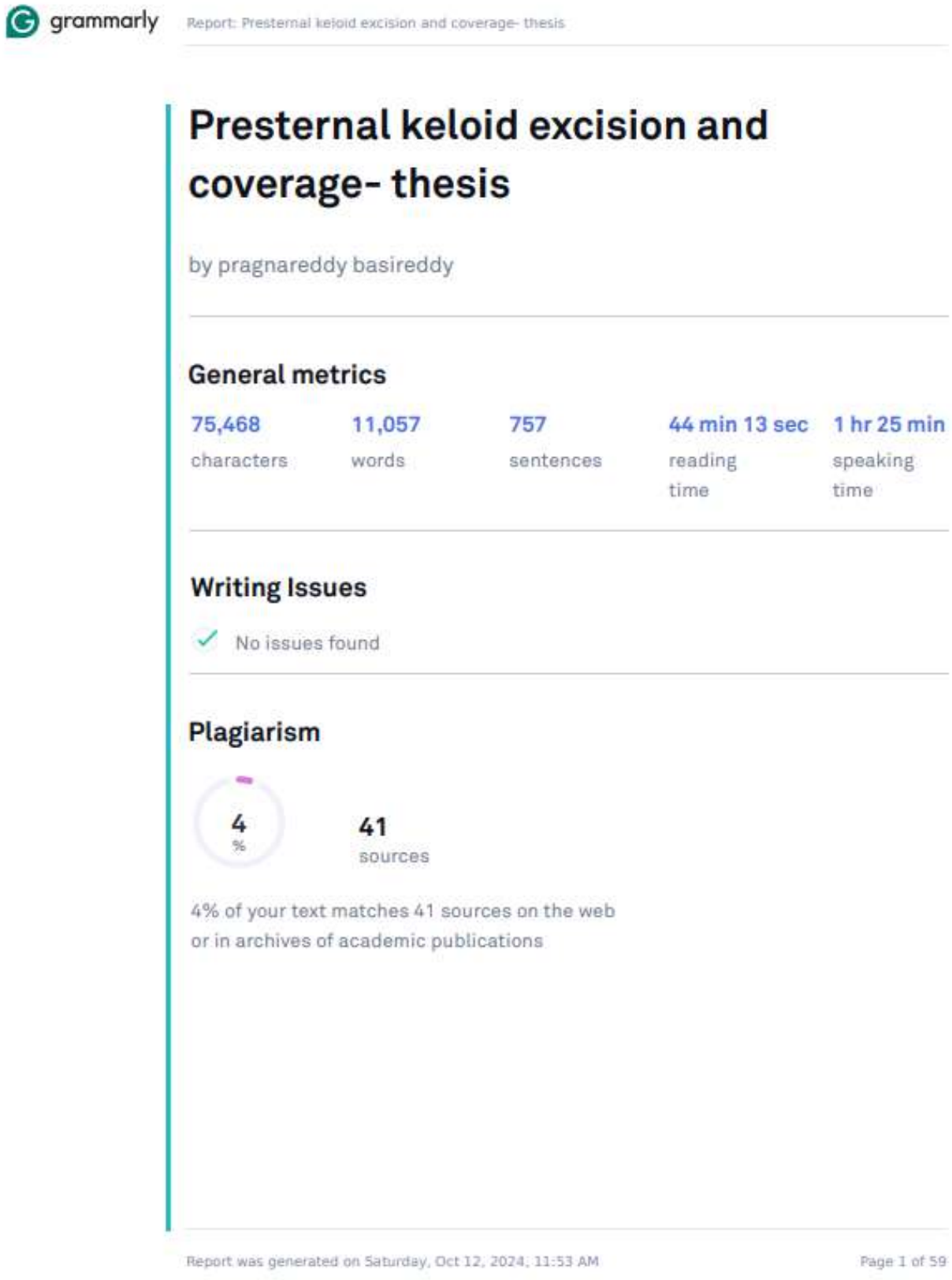
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Dr. B. Pragna Reddy

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LIST OF ABBREVIATIONS

ABBREVIATION	FULL FORM
HTS	Hypertrophic scar
TGF-ß	Transforming growth factor - ß
MMP	Matrix metalloproteases
IL-6	Interleukin - 6
CGRT	Calcitonin gene-related peptide
IPL	Intense pulse laser
AFR	Ablative fractional resurfacing
PDL	Pulsed dyed laser
5FU	5-Fluoro uracil
CAV-1	Caveolin 1
IAP	Integrin associated protein
POSAS	Patient and observer scar assessment scale
DRM	Dermal regeneration matrix
STSG	Split Thickness Skin Graft
OPD	Out Patient Department

Introduction

INTRODUCTION

Wound healing is an intricate and complex series of processes comprising overlapping phases of inflammation, granulation tissue formation, and tissue remodelling resulting in restoring tissue structure integrity. Abnormal wound healing can give rise to keloids, benign dermal fibroproliferative nodular lesions that grow over time, extend beyond the original site of injury, and occur after impaired wound healing. [1].

Collagen synthesis and degradation take place in a strictly regulated state of equilibrium. Loss of this equilibrium results in abnormal tissue repair. Excessive collagen synthesis and degradation may lead to one of the most problematic sequels in clinical practice. Keloid scars are one of the most challenging problems for physicians and surgeons. Numerous methods have been tried to treat these scars, with differing degrees of success.

Keloids grow and spread, i.e., as a “crab’s claw.” Keloid growth resembles malignant tumors, except keloids do not invade other organs. As keloids tend to occur on high-tension sites such as the anterior chest and the scapular region, stretching tension is undoubtedly linked to keloid formation, even if the physiological mechanism behind this development pattern is still unclear [2].

The anatomical location of a keloid appears to alter its morphological characteristics. Some keloids can develop spontaneously; however, most occur after local trauma and other events, including inflammation, surgery, burns, elective surgery, foreign body reactions, acne, insect bites, vaccinations, or mechanical force after the initial insult and rarely regress [3], [4]. The formation of keloids is affected by local skin tension, family history, age, site, and even the immune function of the human body [5].

It has been proposed that the mechanical tension placed on a healing wound results in keloid formation [6]. Indeed, mechanical tension drives not only fibroblast proliferation and collagen synthesis but also dermal remodeling [7]. Anecdotal evidence indicates that aberrant scars are seldom formed by incisions parallel to skin tension lines [8].

Chest keloids are common in clinical practice; an earlier study showed that nearly 50% of all keloids occur in this location [9]. Of all the growing sites of the keloid, the chest is the most common site because it possesses skin tension. The tension load in this area is due to the frequent movements of the upper limbs and the respiratory movements. These movements stretch the skin of the anterior chest horizontally. When this cyclical tension is imposed on the anterior chest wounds, there is an exacerbation and prolongation of the inflammation in the reticular dermis of the wound [10].

Folliculitis and acne are also known for triggering the development of keloids on the anterior chest. In addition, the skin tissue in the chest has much less mobility than other sites of the human body [11]. Remarkably, the cyclical skin stretching that occurs during daily body movements is a substantial factor in the causation of keloids[10].

It is a source of distress to the patient, as even though it is not cancerous, it grows to enormous sizes and causes bleeding, itching, and searing pain in addition to being a cosmetic defect. Treatment is a frustrating experience for surgeons, as keloids have a marked propensity to recur after excision, the recurrence rate being as high as 45% to 100% [12].

The shape and size of the keloids are often different among the patients. Some small keloids are round and oval. These can be removed directly in one surgery. Others are butterfly or dumbbell-shaped with skin extensions laterally. The conventional approach to keloid removal is surgical excision [13]. However, excision creates a new wound and can result in a

similar or larger keloid [14]. Lack of skin tissue to cover the wound after resecting the keloid lesion remains one of the biggest problems in keloid surgical treatment [15].

Various methods can be used for the surgical removal of keloids depending on the size of the keloid, anatomical location, skin type, and age of the patient. These include excision with linear closure, skin grafting, W-plasty, Z-plasty, and flap coverage. To reduce the risk of keloid recurrence, the surgeon performing the excision should establish tension-free wound closure. As a general rule, closure of the wound should be accomplished with minimal tension and sutures, leaving everted wound borders. Z-plasties, three layered sutures, subcutaneous/fascial tensile reduction sutures or local flaps or distant flaps can be employed on a case-to-case basis.

Surgical excision is not recommended as a monotherapy as it results in high recurrence rates in the range of 45%–100% [16]. Surgical excision is frequently combined with other therapeutic treatments to improve postoperative surgical results. These include pressure garments, silicone gel sheet application, intralesional steroid injections, and other medications. However, these have yet to show appreciable efficacy in control rates.

Delays in epithelialization have been linked to a higher incidence of keloids. Consequently, it's imperative to promote quick re-epithelialization with regard to physiological processes and skin structure [17]. The possibility of recurrence thus poses a serious risk to the effectiveness of therapy. Raising patient awareness of the notion that recurrence is more prevalent in body parts under mechanical stress is essential.

Review of literature

REVIEW OF LITERATURE

Keloid has been one of the most challenging clinical problems for many years. Most physicians recommend that management of the keloid depends on the patient's circumstances and evidence-based findings. Keloids are pathological scars extending beyond the original wound borders, which is common in Asians. As a site with high tension, the anterior chest accounts for 48.9% of keloids, according to a previous report [9].

DEFINITION OF A SCAR: A scar is a macroscopic disruption of the typical structure and function of the skin resulting from a healed wound.

NORMAL PROCESS OF WOUND HEALING: A normal restorative response to tissue damage is wound healing. It has 3 classic phases.

A) Inflammation

B) Proliferation

C) Maturation.

INFLAMMATION: Skin injuries cause disruption of blood vessels and tissue, directly exposing the extracellular matrix to platelets. Platelets release cytokines such as PDGF, TGF – β, serotonin, and fibronectin. A fibrin clot is formed, which acts as a scaffold for neutrophils, monocytes, macrophages, and lymphocytes, which release a number of cytokines.

PROLIFERATION: Proliferation includes a) Epithelisation, b) Fibroplasia c) Angiogenesis. Fibroblasts and endothelial cells proliferate as a result of VEGF and TGF-β. The formation of early granulation tissue is marked by myofibroblasts with high α smooth muscle actin levels. Then, the epithelial cells adjacent to the wound proliferate and migrate [18].

MATURATION: This is characterized by the reorganization of collagen. The final matrix comprises glycosaminoglycans, proteoglycans, and collagen type 1. It replaces the early matrix, which comprises fibronectin and collagen type 3.

CLASSIFICATION OF SCARS:

1. Fine line scars: Eg: surgical scars.
2. Wide stretched scars: Eg: Abdominal striae of pregnancy.
3. Atrophic scars: Eg. Chicken pox scars.
4. Scar contractures: Eg. Burn injury.
5. Raised skin scars:

   A) Hypertrophic scars – raised scars that remain within the boundaries of the wound.

   B) Keloidal scars – raised scars that spread beyond the boundaries of the wound. Intermediate scars: scars that are difficult to categorize [19].

KELOID DEFINITION: A keloid may be defined as a benign growth of fibrous tissue developing from an abnormal healing response to a cutaneous injury, extending beyond the original borders of the wound or inflammatory response [20].

HISTORY:

Initial descriptions of keloids were found in an Egyptian papyrus in 1700 B.C. These lesions were referred to as "cancroide" by Jean Louis Alibert (1768–1837) when he described them in 1806. To avoid confusion with cancer, he changed the name to “Cheloide.” The word is derived from the Greek “chele,” meaning “crab’s claw,” and the suffix “oid,” meaning “like.” Yorubas, a tribe from Nigeria, had the custom of facial markings and ear piercing. They described the familial occurrence of keloids as early as 800 A.D. In pre-Columbian times, the Olmec people of Mexico decorated themselves with keloid scarification. The women of Nubia-Kush in Sudan are intentionally scarified with facial keloids as a means of decoration.

Kischer and Brody identified collagen nodules as the distinctive structural unit of keloids and hypertrophic scars. Mature scars lack the nodule and are composed of unidirectional collagen fibrils in a well-defined orientation and a high density of fibroblasts. Furthermore, the thicker epidermal cell layer, high mesenchymal cell density, and rich vasculature of keloids and hypertrophic scars set them apart from healthy skin. Keloids and hypertrophic scars are associated generally with HLA-B14, HLA-B21, HLA-BW16, HLA-BW 35, HLA-DR 5, HLA-DQw3 and blood group A [21].

ETIOLOGY: The predisposing factors include:

a) Trauma

b) Skin tension

c) Infection

d) Autoimmune phenomenon

e) Hormonal factors

f) Genetic factors

f) Drugs

g) foreign material

h) Racial factors

i) Climate.

PATHOGENESIS: The pathogenesis of keloid is complex. The balance between collagen synthesis and degradation is maintained by matrix metalloproteinases and tissue inhibitors of matrix metalloproteinases. This, in turn, is controlled by TGF - β. There are three varieties of TGF-β: 1, 2, and 3. Increased levels of types 1& 2 lead to keloid formation as it inhibits MMP'S

and potentiates TIMP'S.TGF –β Type 3 is found to play a protective role antagonising the action of 1&2 types [18] . Mannose 6 phosphate also inhibits TGF-β types 1&2. There are various other studies that suggest a role for the Plasminogen–Plasmin system in the pathogenesis of keloid. Plasmin is found to activate TGF-β. Activin, another protein of the TGF -β superfamily stimulates the proliferation of fibroblasts and hence plays an important role. Cytokines like IL-6, TNF α, were found to be increased in keloids. So, cytokines are thought to play a part in the evolution of keloids. Recently a new theory called as the neurogenic inflammation hypothesis has been put forward. This states that mechanical stress stimulates nociceptors [22] on sensory fibers in the skin, which release neuropeptides like substance P, CGRP, and TGF -β, which in turn activates fibroblasts.

CLINICAL FEATURES:

Keloids appear 3–4 months after an inflammatory stimulation. The lesions are complex, pink or red plaques that spread beyond the boundaries of the original lesion and keep growing for months or even years. They could take on the shape of a dumbbell or become irregular and asymmetrical.

SYMPTOMS: commonly observed symptoms are Pruritus (80%), pain (50%), and burning sensation.

HISTOPATHOLOGY OF KELOID:

The epidermis is normal. There is no scarring of the papillary dermis. Collagen bundles or whorls of collagen with peripheral capsule-like bands are present. These are stretched and aligned in the same plane as the epidermis. The center of the lesion is relatively acellular. The collagen fibers are large, thick, and hyalinised. A horizontal fibrous band is seen in the upper reticular dermis. There is a tongue-like advancing edge beneath a normal epidermis and papillary dermis, in contrast to hypertrophic scars in which there is no advancing edge [23].

BIOCHEMICAL CHARACTERISTICS:

By using the hydroxy proline measurement method, total collagen is found to be increased. Increased proteoglycan content is also observed using the glucosamine estimate method. It is discovered that keloid has a high water content, which is determined by comparing the wet and dry weight of scar biopsies. Collagen that is soluble in pepsin is less abundant in keloids. Since cross-linked collagen is represented by pepsin-soluble collagen, cross-linking is impaired in keloids [24].

ASSOCIATIONS OF KELOID:

- Dupuytren's contracture,
- Ehlers Danlos syndrome,
- Rubinstein Taybi syndrome,
- Dubowitz syndrome,
- Pachydermoperiostosis,
- Geominne syndrome,
- Turner's syndrome,
- Noonan's syndrome,
- Acne conglobate,
- Hidradenitis suppurativa,
- Pilonidal cysts,
- Pseudofolliculitis barbae[25].

PREVENTION:

1. Pre-surgical evaluation of potentially high-risk patients by clinically evaluating their previous surgical scars

2. Family history of keloids should be looked for.

3. Patients who are prone to keloids should refrain from having unnecessary cosmetic surgery.

4. Appropriate safety measures should be implemented during surgery, such as aligning incision lines parallel to skin wrinkles to minimize wound tension.

5. As much as feasible, incision sites above the joints or in the mid-chest should be avoided.

6. It is recommended to utilize non-absorbable sutures instead of buried absorbable sutures.

7. Electrosurgical device use needs to be limited.

Treatment modalities available are as follows:

1.Compression therapy.

2. Cryotherapy.

3. Intralesional therapies:

a) Intralesional Triamcinolone acetonide.

b) Intralesional 5- Fluorouracil

c) Intralesional Verapamil

d) Intralesional Interferon

e) Intralesional Bleomycin

4. Silicone gel sheets

5. Lasers:

a) Pulsed dye laser

b) ND: YAG laser

c) Co2 laser

d) Argon laser

6. Surgical excision.

7. Combination therapies:

a) Triamcinolone injections, either intraoperatively or postoperatively, can be used in conjunction with surgical excision.

b) Radiation therapy after surgical excision

c) Silicone gel sheets application and silicone gel massage after surgical excision.

d) Silicone gel sheets and intralesional triamcinolone are administered after cryotherapy.

8. Miscellaneous therapies:

a) Topical tamoxifen – Nonsteroidal antiandrogen that decreases the expression of TGF- β.

b) Onion extract gel.

c) Retinoic acid – reduction of fibroblast proliferation and collagen synthesis.

d) Botulinum toxin

e) Pentoxifylline

f) Colchicine.

g) Tacrolimus.

RADIATION THERAPY:

Radiation therapy consists of applying ionizing radiation to keloids using different therapeutic sessions and on different days. This therapy inhibits fibroblast proliferation and

stimulates fibroblast differentiation [26]. Administered soon after surgical excision, this approach has shown high efficacy in decreasing keloid recurrence, as several studies have demonstrated [27].

Radiotherapy as an adjuvant for operated keloids can be performed using different techniques, including

1. TGF-β therapy,
2. conventional X-ray,
3. single-dose radiotherapy, and
4. electron-beam radiotherapy.

Because electron irradiation has less penetration into deeper surrounding tissues and a better dosage distribution inside the target tissue, it is preferable to conventional irradiation [28]. Patients respond effectively to electron irradiation. However, temporary hyperpigmentation of the treated area and persistent peeling for around three months are possible side effects. According to a study, cells exposed to radiation may have an increased risk of cancer [26].

The dose used for treating keloids should be adapted according to the location of the lesion, and the highest doses should be used at high-risk sites. The effectiveness of this approach in keloid prevention depends on the biologically effective dose, and no consensus has been reached on the best dosage. A minimum follow-up of 2.5 years with postoperative electron irradiation is necessary to achieve satisfactory results regarding scar quality and reduction of recurrence [28].

Mankowski et al. conducted a literature review of 72 studies to compare the clinical outcome of different forms of radiation treatment used for the management of keloids [29]. The meta-analysis demonstrated that radiation used as monotherapy yielded higher rates of recurrence (37%) compared to combinational therapy with post-surgery excision (22%).

Comparison between the different radiation-based treatments revealed that the lowest rate of recurrence was observed with brachytherapy (15%), followed jointly by X-ray (23%) and electron beam (23%). The authors also reported that the recurrence rate depended on the anatomical site of the keloid, with chest keloids having the highest recurrence rate [30].

LASER THERAPY:

Intense pulsed light (IPL), carbon dioxide ablative fractional resurfacing (AFR), and pulsed dye laser (PDL) are examples of targeted therapies. PDL or AFR are recommended for smaller keloids resistant to 5-FU, intralesional corticosteroids, and silicone gel sheeting because they improve the aesthetic results and lessen discomfort. Combined treatments like PDL and AFR are preferred over single therapies[31].

Edema, mild to moderate erythema, and transitory purpura are the most frequent side effects of PDLs. Early in the healing process, skin scabbing or blistering may happen. Additionally, hypo- or hyperpigmentation may occur, particularly in those with darker skin. Ulcers, post-inflammatory hyperpigmentation, and delayed healing are all possible effects of AFRs [32].

DERMAL REGENERATION MATRIX: The dermal regeneration matrix (DRM) (Integra®) consists of a bilaminar structure formed by a dermal component (bovine collagen and chondroitin6-phosphate) and an epidermal component made with a 100 µm thick synthetic silicone sheet [33]. It has a three-dimensional structure with 50 ± 20 µm pores and resembles normal skin. The matrix is completely degraded after 30 days. The outer silicone layer acts as a protective barrier and prevents the loss of liquids. After neovascularization, the silicone sheet is replaced with a thin autologous epidermal graft, and the epidermal cells in the grafts proliferate and attach to the neo-dermis [33].

DRMs promote wound healing without wound tension, do not trigger immune responses, contain a thin epidermal graft, do not require adjuvant therapies, and the results resemble healthy skin. DRMs are sterile, and their implantation is relatively simple. The disadvantages are its high cost, the infection risk between the matrix's two layers, and the need for two surgical procedures [34].

A study conducted by Nguyen KT et al. evaluated the use of DRMs for keloids and found that the aesthetic results were acceptable and that the skin remained flat and infection-free. Moreover, there were no long-term complaints or evidence of scarring at donor sites. Limitations included a small sample size and a follow-up period of <24 months [34].

COMPRESSION THERAPY:

Pressure therapy has been used to treat and manage keloids and hypertrophic scars for decades [35]. It has been routinely employed as a first-line treatment in the treatment of hypertrophic scarring resulting from burns. The efficacy of pressure therapy depends mainly on the anatomical location of the scar, with trunk and limb areas being more appropriate sites for pressure therapy. This includes

a) Button compression.

b) Pressure earrings.

c) Elastic adhesive bandages.

d) Zinc oxide adhesive bandages [36]

MECHANISM OF ACTION: It decreases oxygen tension through occlusion of small vessels and subsequent reduction in tissue metabolism, fibroblast proliferation, and collagen synthesis. Capillary pressure greater than 4mm Hg is applied for > 23.5 hours/day. This has to be continued for 6 to 12 months [37], [38]. Pressure therapy is tolerated better and is devoid of

the pain often associated with intralesional therapies and hence can be considered a good adjuvant therapy for keloid scars.

CRYOTHERAPY: It is a common modality that is used to treat hypertrophic scars and keloids. Substances which are used in cryotherapy are

a) Liquid nitrogen - - 196 degrees Celsius.

b) Ice - 0 degree Celsius

c) CO2 slush - - 20 degree Celsius

d) CO2 snow - -79 degree Celsius

e) Nitrous oxide - -90 degrees Celsius

MECHANISM OF ACTION: Destruction of keloidal fibroblasts by

a) Intracellular and extracellular ice formation.

b) Osmolarity changes.

c) Apoptosis.

d) Thermal shock.

e) Vascular changes.

f) Coagulation of proteins.

g) It also causes local edema and gives an anesthetic effect for subsequent injection of intralesional steroids.

Macroscopic changes observed after cryotherapy are that, during and immediately after the application, a white ice field is formed. A minute later, after thawing, a purplish violet color develops at the periphery and moves centrally. And the deeper tissues become pale. In one or

two days, a hemorrhagic blister on an erythematous base develops in the center. In a week, blister forms an eschar. Eschar separates spontaneously in 2 weeks.

SIDE EFFECTS:

Acute: pain, headache, oedema, blister, fever, syncope.

Chronic: hypopigmentation, depigmentation, hyperpigmentation, milia, arthralgia, nerve damage, paraesthesia, atrophy.

TECHNIQUES AVAILABLE:

a) Cryospray

b) Cryoroller.

c) Cryoprobe.

d) Intralesional cryosurgery[39]

INTRALESIONAL CORTICOSTEROID INJECTION: It is widely used in treating keloids. The preferred steroid is Triamcinolone acetonide. It is used in a concentration of 10 to 40 mg/ ml, depending on the size and location of the lesion.

METHOD OF ADMINISTRATION: Triamcinolone acetonide 40 mg/ ml is injected alone or in combination with lignocaine 1%, with a 25-to-27-gauge needle attached to an insulin syringe. The needle is introduced into the lesion at an angle of 30 to 45 degrees, with the bevel of the needle pointing downwards. Inject only after aspiration.0.05 to 0.1ml is injected at each site sequentially by multiple puncture technique to cause blanching. Blanching should not be allowed to spread to the adjacent tissue. Pressure hemostasis is achieved, and dressing with antibiotic ointment is given.

Postoperatively, antibiotics, analgesics, and anti-inflammatory drugs are given. The injections are given at intervals of 3 to 4 weeks. The rate of response to treatment is 50–100%, and the 5-year recurrence rate is ≤50% [40].

MECHANISM OF ACTION:

a) Inhibits fibroblast growth.

b) Inhibits collagen and glycosaminoglycan synthesis.

c) Decreases TGF-β and increases basic- FGF production.

d) Decreases the release of inflammatory mediators.

e) Decreases alpha 2 macroglobulin levels (which inhibits collagenase).

f) Vasoconstrictive effect [41], [42], [43], [44].

SIDE EFFECTS:

a) Pain during injection.

b) Skin atrophy.

c) Depigmentation, hypopigmentation

d) Telangiectasia.

e) Necrosis and ulceration.

SILICONE GEL SHEETS: Silicones are synthetic polymers based on dimethyl siloxane monomer. They have a repeated structural unit Si0 (CH3)2. 3 types of silicones are used, namely fluids, gels, and elastomers. Since the 1980s, silicone-based products have been used in the treatment of keloids and hypertrophic scars, with silicone gel or silicone gel sheeting

considered as first-line therapy for minor keloids and hypertrophic scars [35]. There are various other forms of silicone, including creams, sprays, gel cushions, and liquids [45].

MECHANISM OF ACTION: It is postulated that it causes hydration and modulates the effect of keratinocytes on fibroblasts. Hydration is thought to result in decreased capillary activity with an ultimate reduction in collagen deposition via decreased synthesis of pro-inflammatory cytokines. It is also thought to alter oxygen tension in tissues. Static electricity that develops at gel dressings and skin interface or the effect of temperature changes leads to blockage of growth factors, resulting in diminished fibroblast activity and collagen breakdown.

MODE OF USAGE: The sheet is trimmed from the standard-sized sheet to match the specific scar. The sheet should extend at least one to one and a half inches around the lesion for a better hold. It is directly applied over the lesion and kept in place with a micropore tape. It is worn 12-24 hours daily for 2-3 months. Each sheet will last for 28 to 30 days [46], [47].

Studies have shown that the beneficial effects of silicone gel sheets include pain reduction, tenderness and pruritus, and flattening of the keloid [46]. Studies have also demonstrated an improvement of up to 90% in keloid scars after using silicone gel sheeting and a decrease in the incidence rates of keloids and hypertrophic scars after surgery [48]. A recent meta-analysis [49] and Cochrane review [50] evaluated the published studies supporting the efficacy of silicone gel sheeting in the treatment and prevention of keloid and hypertrophic scarring, found that they provided weak evidence and were of poor quality.

To limit skin stretching and external mechanical stimuli during wound healing/scarring, wounds or scars should be covered by fixable materials such as tape, bandages, garments, or silicone gel sheets. A randomized controlled trial showed tape fixation helping to prevent HTS formation post-Caesarean section in 70 subjects: the scar volume was significantly lowered when the paper tape was applied [51]. Other randomized controlled trials

show silicone gel sheeting significantly reducing the incidence of HTS or keloids [25]. The computer analysis of mechanical force conditions around scars has also shown that silicone gel sheeting reduces the tension at the scar edges[52].

Hsu C K, Lin H H, Harn H I, et al. Caveolin -1 (CAV1) has been linked to the regulation of focal adhesions and integrin-mediated actin remodeling and has been shown to play an important role in keloids' aberrant responsiveness to mechanical stimulation [49]. Thereafter, peptidergic drugs targeting CAV1 may be a promising strategy. CD47, known as integrin-associated protein (IAP), has shown an anti-fibrotic effect in scleroderma and other fibrosis-related diseases [53].

A prospective study of 47 patients of presternal keloids conducted by Cheruvu VPR et al. found that following three sessions of intralesional triamcinolone acetonide and hyaluronidase injections, there was an improvement in the patient's symptoms, as evidenced by the reduction in the mean pruritis scores and pain scores indicating decreased inflammatory activity within the presternal keloid. This suggests that the intralesional treatment with a combination of triamcinolone acetonide and hyaluronidase was effective in reducing the symptoms of presternal keloids like pruritis and pain, but it cannot lead to a significant reduction in the size of large-sized or long-standing lesions [54].

Ogawa R et al., in their study based on evidence-based algorithms, have treated abnormal scars, including keloids and hypertrophic scars, with a multimodal approach that employs traditional methods, such as surgical removal, postoperative radiotherapy, corticosteroid injection, laser, and silicone gel sheets [12]. As a result, the rate of abnormal scar recurrence has decreased dramatically over the past 10 years [55], [56]. With regard to keloids, the treatment method of choice depends on whether the keloids are small/single or large/ multiple[12].

Small/single keloids can be treated radically by surgery plus adjuvant therapy (which includes radiation or corticosteroid injections) or by nonsurgical monotherapy (which includes corticosteroid injections, cryotherapy, laser, and anti-tumor-immunosuppressive agents such as 5- fluorouracil). Large/multiple keloids are difficult to treat radically and are currently only treatable by multimodal therapies that aim to relieve symptoms. Regardless of the treatment method employed, a long-term follow-up is recommended. Moreover, conservative therapies (which include gel sheeting, taping fixation, compression therapy, external/ internal agents, and make-up (camouflage therapy) should be administered on a case-by-case basis [57].

A recent case series study conducted by Arima et al. in which 141 patients with anterior chest wall keloids were given a treatment protocol consisting of complete excision, Z-plasty, postoperative adjuvant radiotherapy, and postsurgical wound self-management, reported excellent outcomes with a recurrence rate of only 10.6%. The use of steroid tape and injections helped to resolve the recurrence of keloids [58].

Ogawa et al. in their research suggest that mechanical force and hypersensitivity to mechanical force are major causes of abnormal scarring and that cyclically applied mechanical forces may induce continuous skin inflammation and mechanosignaling pathway activation [59]. Moreover, the skin stiffness at the keloid circumference correlated directly with the degree of skin tension. These observations explain why keloids generally stop growing in their central regions and why keloid expansion occurs in the predominant direction(s) of skin pulling.

Verhaegen [60] demonstrated that wide scar or wound dehiscence may become the consequence if the suture strength cannot equal the wound-shearing forces before the scar maturation. Three-layer suture in the subdermal, dermal, and epidermal layers was first used

by Hyakusoku and Ogawa [61]. They also strongly support that skin tension is closely associated with the pattern and degree of keloid growth. In particular, their finite element analysis of the mechanical force distribution around the keloids revealed high skin tension at the keloid edges and lower tension at the keloid centers [62]. Real-time RT PCR analyses showed that cyclically stretched skin expresses growth factors and neuropeptides more strongly than statically stretched skin [63], [64].

Flap Surgery for Keloid Reconstruction:

Keloids can be treated surgically in two ways: they can either be radically resected or undergo mass reduction [12]. For both types of approaches, skin grafting or flap transfer [65] maybe required if the keloid is difficult to excise completely and suture directly. However, two problems are associated with skin grafting, namely keloid recurrence at the skin graft's margins and depigmentation of the skin graft's center. Computer simulation studies have suggested that the tension on the edge of the keloid will be reduced if there is soft tissue under the keloid [57].

Flaps have multiple benefits in treating a chest wall keloid. With sufficient skin and soft tissues, a flap could maximally reduce the skin tension [66]. It was reported that the width and surface area of the perforator flaps had expanded 120% to 130% at 7 months after they were used for broad scar contractures [60]. Thus, for the chest wall wound post–keloid resection, local flaps are the best option when it is difficult to close it primarily.

It has long been recognized that the IMA perforators will support the skin of the anterior chest wall; therefore, there are multiple choices when choosing an IMA perforator flap to cover the defect [66]. A freestyle or pedicled propeller flap based on the fourth or fifth IMA perforator could also be used in such circumstances with the most invisible scar within the inframammary fold [67].

Ogawa R et al. in their study showed that preliminary study on 20 patients with huge keloids who were treated by such flaps and postoperative radiotherapy have shown that all cases had uneventful postoperative courses and keloid recurrence was not observed flap surgery is suitable as a treatment of choice when dealing with severe keloids. In particular, since perforator flaps (especially the perforator pedicled propeller flap) are associated with little donor site morbidity, these sophisticated flaps are used to reconstruct keloids. In the past, keloid reconstruction using flaps was discouraged because it was thought the donor site could develop keloids. However, the development of keloids on the donor site can be prevented using subcutaneous/fascial tensile reduction sutures and post-operative radiotherapy [57].

In 1990 Sullivan et al. developed the Vancouver Scar Scale (VSS), the first widely used assessment to record burn scars using a semi-quantitative approach in order to measure change in scar appearance during healing and treatment [68]. The Vancouver Scar Scale (VSS) uses a numeric score from 0 to 13 to evaluate four variables: vascularity, height or thickness, pliability, and pigmentation. A score of 0 represents normal skin, while 13 represents the worst possible scar [69].

Limitations of VSS:

- The VSS does not evaluate subjective symptoms such as pain, itching, or psychological after-effects, nor does it consider the patient's scar assessment.
- Also, VSS may not be reliable or effective, especially for large or irregular scars.

There are several other scales that entail these requirements, but the Patient and Observer Scar Assessment Scale (POSAS), developed by Draaijers et al. [70], is the most robust instrument for evaluating scars because it also attributes weight to the patient's opinion. POSAS incorporates the concept of the Vancouver Scar Scale (VSS) and also evaluates the

observer and patient, establishing a total score and a general opinion for the result of the two scales [70].

In 2005, Van de Kar et al [71] incorporated a new evaluation parameter to the original scale, totaling six evaluation parameters for both the patient and observer, resulting in the current version of the POSAS. It also includes the subjective symptoms of pain and itching and expands on the objective data obtained from other scales. It comprises two versions of numerical scales, equal and directed for physician and patient use. POSAS has been well used and recommended, mainly because it fulfills the clinical requirements [72].

Demerits of the POSAS scale:

- ★ It lacks functional measurements of whether the pain or pruritus interferes with the quality of life.
- ★ Items represented in this scale may not adequately express the perceptions and concerns of the patients.

Xiao Long et al. proposed an algorithm for the treatment of chest wall keloids[66]. In their study, four hundred forty-five patients (242 males and 203 females) received various treatment methods according to the size, number, and location of the chest wall keloid. Four protocols are available for choosing in this algorithm, and all of the patients received adjuvant radiotherapy of 18 Gy over 2 sessions in the early postoperative period.

- ➢ Protocol 1: keloid resection and direct closure with intradermal double layer continuous suture technique.
- ➢ Protocol 2: keloid resection with a local flap or internal mammary artery perforator flap.
- ➢ Protocol 3: perilesional incision first session of radiotherapy + skin graft + second session.

- Protocol 4: keloid core resection and radiotherapy.

With a mean follow-up time of 13 months (range: 6–18 months), 362 patients participated in the assessment of POSAS with doctors. The recurrence rate was 0.83%. There was an obvious significant difference ($P<0.001$) between the before-surgery score and the after-surgery score from both doctors and patients, indicating that both doctors and patients were satisfied with the treatment effect [66].

We have performed this study to assess the effectiveness of surgical excision of presternal keloids followed by reconstruction in reducing the symptoms associated with these lesions.

Aims and Objectives

AIMS & OBJECTIVES

AIM- To evaluate the effectiveness of the treatment of presternal keloids by excision followed by reconstruction.

OBJECTIVES

To study:

- ★ the demographic features of patients presenting with presternal keloids
- ★ the various forms of reconstruction used after the excision of presternal keloids
- ★ the incidence of complications and the postoperative quality of the scar
- ★ the incidence of recurrence in the follow-up period.

Materials and Methods

MATERIALS & METHODS

STUDY DESIGN

Prospective observational study.

STUDY SETTING

The study was conducted on patients presenting with presternal keloids at the Department of Burns and Plastic Surgery, All India Institute of Medical Sciences, Bhopal.

STUDY DURATION: 21 months (February 2023 to October 2024)

Enrolment period- 9 months

Follow-up duration- 12 months

PLACE OF STUDY: Department of Burns & Plastic Surgery, All India Institute of Medical Sciences, Bhopal.

STUDY POPULATION

Patients presenting to the Department of Burns & Plastic Surgery, AIIMS Bhopal, seeking treatment for presternal keloids and fitting the inclusion criteria, were enrolled in the study.

INCLUSION CRITERIA

1. Patients of all age groups and both genders present with symptomatic presternal keloids with impairment of quality of life due to persistent, uncomfortable feelings such as itchiness or pain or recurrent infections.
2. Failure to respond to conservative therapies
3. Patients who were medically fit for anesthesia and surgery.

4. Patients are willing to participate in the current research with a hand-signed informed consent document.

EXCLUSION CRITERIA

1. Patients with keloids at other sites.
2. Mentally unstable patients with presternal keloids.
3. Patients with unrealistic expectations.

Sample size: The minimum sample size for this study was determined to be 30. Based on the monthly census, the average number of patients coming to the Plastic surgery OPD for treatment of presternal keloids was around 3.3. The total duration of the study was nine months. Therefore, the minimum sample size for this thesis was determined to be 30.

METHODOLOGY:

Thirty-one patients presenting with presternal keloids to our hospital's Burns and Plastic Surgery department from February 2023 to October 2024 were recruited for inclusion in the study. Diagnosis of presternal keloid was made by history and clinical examination. After obtaining informed consent, we evaluated the patient as here under.

CLINICAL EXAMINATION:

After the patient's enrollment, a clinical assessment was performed per the case record form attached to the annexure. A thorough history of -

- Onset of the lesion, whether spontaneous or followed by acne, folliculitis, insect bite, trauma, surgery was taken to assess the etiology of the disease.
- duration & progression of lesion,
- associated symptoms,

- family history,
- the site, number, size, consistency, and color of the lesions

A meticulous general and systemic examination was performed to look for associations. A complete local assessment of the anterior chest region was carried out. Routine blood and radiological investigations were done (complete blood count, PT/INR, liver function test, kidney function test, and viral markers). ECG and 2D-ECHO were done, and a cardiology opinion was obtained before proceeding with surgery in patients with a history of cardiac disease.

The purpose and protocol of the study were explained to the patients in detail. A patient information sheet was presented to the patient in his language. Written informed consent was obtained from the patients for participation in the study. Scoring was performed using POSAS and Likert's scale.

PREPARATION OF THE PATIENT:

Xylocaine sensitivity test was done by injecting 0.2ml of 2% xylocaine subcutaneously on the volar surface of the forearm on each patient to rule out hypersensitivity. Sensitivity testing was also done for an IV antibiotic pre-operatively. IV antibiotic was used according to the departmental protocol. Parts preparation (shaving of hair over chest and abdomen) was done. The surgical procedure was selected depending on various factors, with consideration given to the patient's informed choice. Some factors considered were the size of the lesion, the size of the defect created, and the surgeon's preference.

SURGICAL TECHNIQUES:

The first step was complete resection of the presternal keloid. Intra-operatively, a single dose of Triamcinolone (40mg/ml) injection was given into the margins and floor of the

defect after excision of presternal keloid. After meticulous hemostasis, the defect size was measured with a ruler. The reconstruction mode was decided according to defect size and the available options. The methods of reconstruction used in our study included primary closure, local flaps, and split-thickness skin grafts.

When it was determined that the defect was amenable for primary closure, it was ensured that it was tension-free and done in three layers. The subcutaneous tissues were approximated with a 3-0 Polyglactin suture; the dermal layer was closed with a 4-0 Polyglactin suture, and skin closure was done with a 4-0 Nylon suture. Dressings were done with an antibiotic ointment and sterile gauze.

In cases where local flaps were done, we could primarily close all the donor areas without needing a skin graft. The local flaps included Intercostal perforator-based propeller flaps, Limberg flaps, Advancement flaps, and Keystone flaps. The donor sites of the local flaps were closed in three layers, tension-free. Flap monitoring was done as per the routine departmental protocol. In some cases, a split-thickness skin graft was used to resurface the defect after excision of the presternal keloid. In this case, a bolster dressing was applied over the graft.

ADJUVANT THERAPIES AFTER SURGERY:

Every patient in our study received intraoperative triamcinolone injections. In the postoperative period, four adjuvant treatments were suggested to the patients as follows-

1. Intralesional triamcinolone
2. Silicone gel massage
3. Silicone gel sheet application
4. Radiation

After explaining the pros and cons of each treatment modality, the adjuvant treatment was given as opted by the patients. Sutures were removed on the 10th to 14th postoperative day. All patients were routinely advised to use compression dressings /bandages over the operated sites for 6 to 12 months.

Intralesional Triamcinolone acetonide (40mg/ml): Postoperative patients were treated with an injection of Triamcinolone acetonide 40mg/ml, with a 27-gauge needle attached to an insulin syringe. 0.2 ml was injected in each site ($1cm^2$) until blanching. Multiple punctures were given segment-wise sequentially to cover the entire suture line. Care was taken not to cause blanching of the surrounding area. Pressure hemostasis was obtained, and an antibiotic dressing was used. The patients were given injections at three-week intervals until the scar was flattened or for a maximum of 18 weeks if needed.

After suture removal, silicone gel sheets were applied over the lesions and kept in place with micropore tape. The patients were advised to keep the sheet in place for at least 12 hours daily. Silicone gel massage over the suture lines was advised twice daily.

Upon their choice, for some patients, postoperative radiotherapy was given after obtaining consent. We have given external beam radiotherapy of five cycles of 25 gy from postoperative day 3 to day 7.

FOLLOW UP AND EVALUATION OF THE PATIENT

Flap necrosis, hematoma or seroma formation, and infection/discharge were looked for in the immediate postoperative period. Clinical photographs were taken pre-operatively, in the immediate postoperative period, at suture removal and follow-up visits. The follow-up visits were weekly for the first two weeks, once a month for three months after that, and once in 2 months for one year. During each visit, a note was made of

- scar widening or hypertrophy

- any local complaints like pain, pruritus, and hypopigmentation.

ENDPOINTS

All enrolled patients were assessed for the following endpoints: -

Primary Endpoints

1. Flap survival

2. Complete healing of operated sites.

3. Any complications at donor and recipient sites.

4. Symptomatic relief.

Secondary Endpoints

1. Quality of Scar

2. Aesthetic outcome

MEASURES/ SCALES:

POSAS and Likert's scoring was done pre-operatively and at the end of one year.

1. The patient and observer scar assessment scale (POSAS):

POSAS is used to assess the scar quality. It consists of two numeric scales: the Patient Scar Assessment Scale (patient scale) and the Observer Scar Assessment Scale (observer scale). POSAS is free of cost in the public domain after providing the intended purpose of use [72]. Scoring ranges from 6 to 60.

The questions asked to the patient in POSAS patient score were:

- Is the scar painful?

- Is the scar itching?
- Is the color of the scar different?
- Is the scar stiffer?
- Is the thickness of the scar different?
- Is the scar irregular?

Scar characteristics like -

1. vascularity,
2. pigmentation,
3. relief,
4. thickness,
5. flexibility, and
6. surface area

are scored by the observer in a range of 1 to 10. A score of 1 for each component denotes the normality of the skin as perceived by the patient and observer in their respective scales. At the same time, a maximum score of 10 for each parameter represents the worst scar. Overall, the scar's patient and observer opinion scores were from 1 to 10 in the pre-operative period compared to the one-year postoperative period.

2. Likert's scale:

It was used for measuring aesthetic outcomes. A maximum score of 5 is given when the patient is delighted with the result, and a minimum of 1 when the patient is unsatisfied. [73]

RECURRENCE:

According to the existing literature, presternal keloids have a high recurrence rate after surgical excision [16]. Considering this aspect of the natural history of presternal keloids, in our study, we have defined recurrence at one year as a POSAS score which is the same or worse than the preoperative score.

STATISTICAL ANALYSIS:

The collected data was entered into Microsoft Excel and then analyzed and statistically evaluated using the SPSS-25 version. The normality of each variable was assessed by using the Kolmogorov- Smirnov test. Quantitative data was expressed by mean and standard deviation, and the difference between means of pre and post-test was tested by the Wilcoxon signed rank test. In contrast, the Kruskal Wallis H test was used to compare the mean of more than two groups. Qualitative data were expressed in percentages. A 'P' value of less than 0.05 would be considered statistically significant.

Results

RESULTS

This single-center study was conducted in the Department of Burns & Plastic Surgery, All India Institute of Medical Sciences, Bhopal. A total of 31 patients with presternal keloids were included in the study. All the patients underwent excision of the presternal keloid followed by reconstruction either by primary closure, skin grafting, or locoregional flaps.

The observations and results obtained are described as follows:

1. Socio-demographic profile of the study participants

2. Clinical profile of the study participants

3. Surgical outcome and complications

4. Aesthetic outcomes one year after surgery

Age distribution of the study participants:

The age of the patients ranged from 23 to 60 years. Most of the study patients were 21-40 years old. The maximum number of patients were in age groups of 21-30 years and 31-40 years, comprising 33.3% each, followed by 25.8% of patients between 41-50 years and 9.7% of patients between 51-60 years, as demonstrated in Table 1 and Figure 1. The mean age of the study patients was 37.45±10.44 years.

Table 1: Age-wise distribution of study subjects (n=31)

Age group	No.	%
21-30 years	10	32.3
31-40 years	10	32.3
41-50 years	8	25.8
51-60 years	3	9.7

The mean age was 37.45±10.44 years

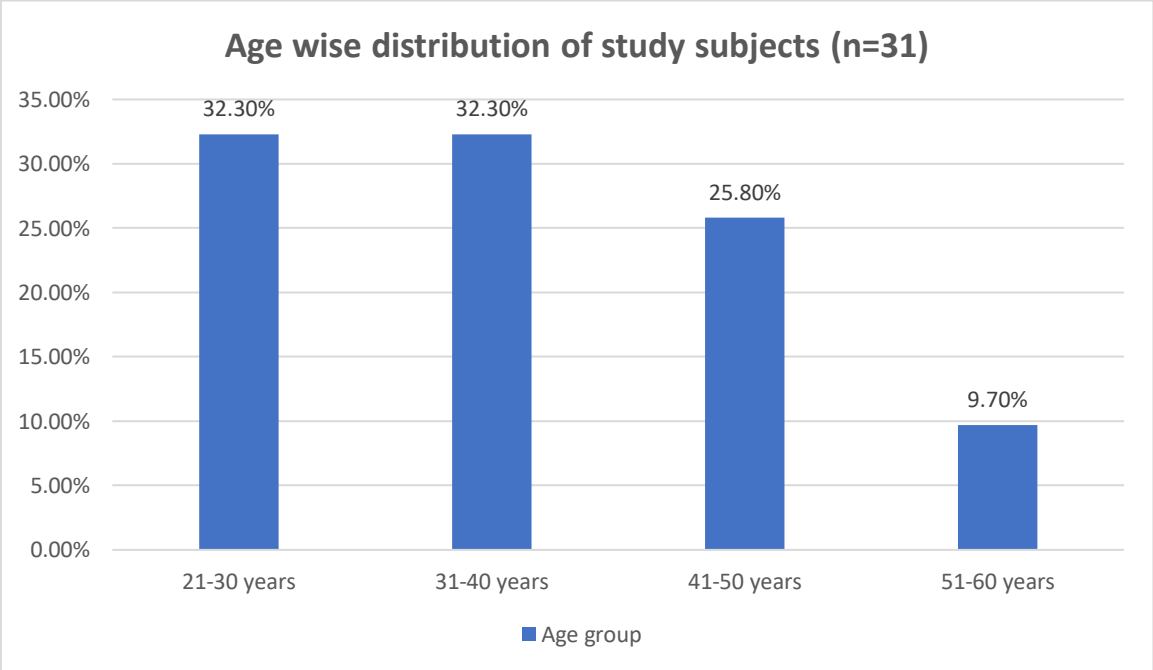


Fig. 1: Age Distribution

Gender distribution of the participants:

Most of the study patients were males, comprising 87.1% of the population, while females comprised 12.9%, as depicted in Figure 2 and Table 2.

Table 2: Gender-wise distribution of study subjects (n=31)

Gender	No.	%
Female	4	12.9
Male	27	87.1

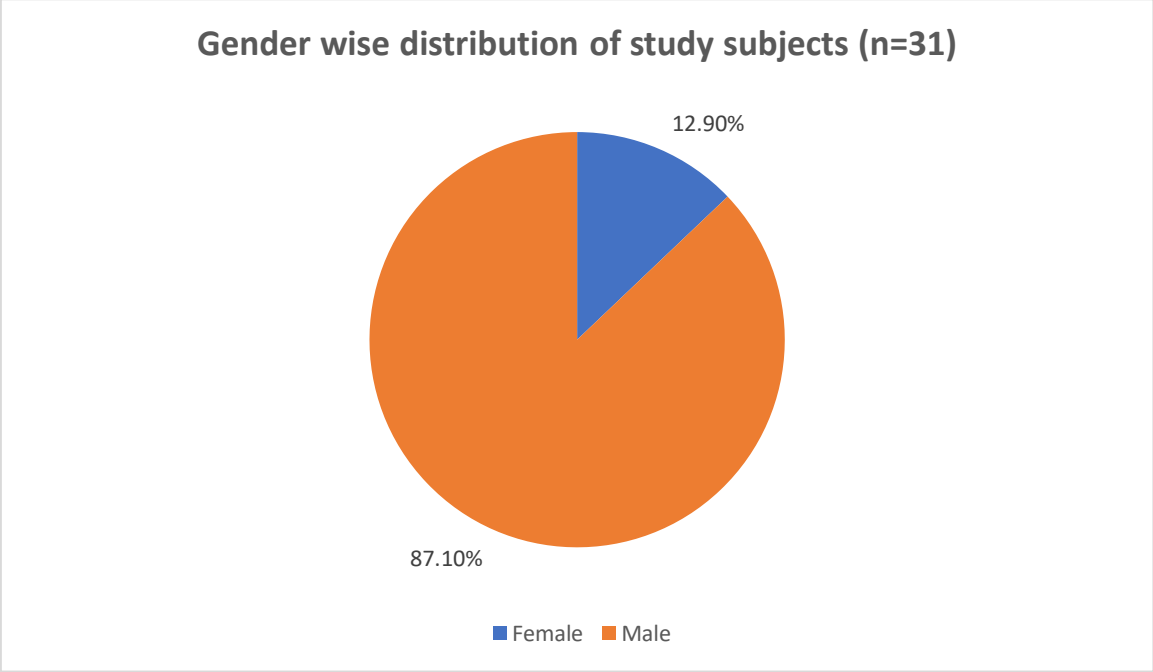


Fig 2: Gender distribution

Treatment history:

In our study, most patients had no prior history of intralesional Triamcinolone injection 11 (35.5%), while 7 (22.6%) had taken more than 5 doses. 3.2% of enrolled patients had a history of two injections, 16.1% of the patients had three injections, 19.4% of patients had 4 injections, and the other 3.2% of patients had taken 5 intralesional injections previously - table 3 and Fig.3.

Table 3: Treatment history (no. of doses of intralesional Triamcinolone injection) in study subjects (n=31)

no. of doses of intralesional Triamcinolone injection	No.	%
0	11	35.5
2	1	3.2
3	5	16.1
4	6	19.4
5	1	3.2
>5	7	22.6

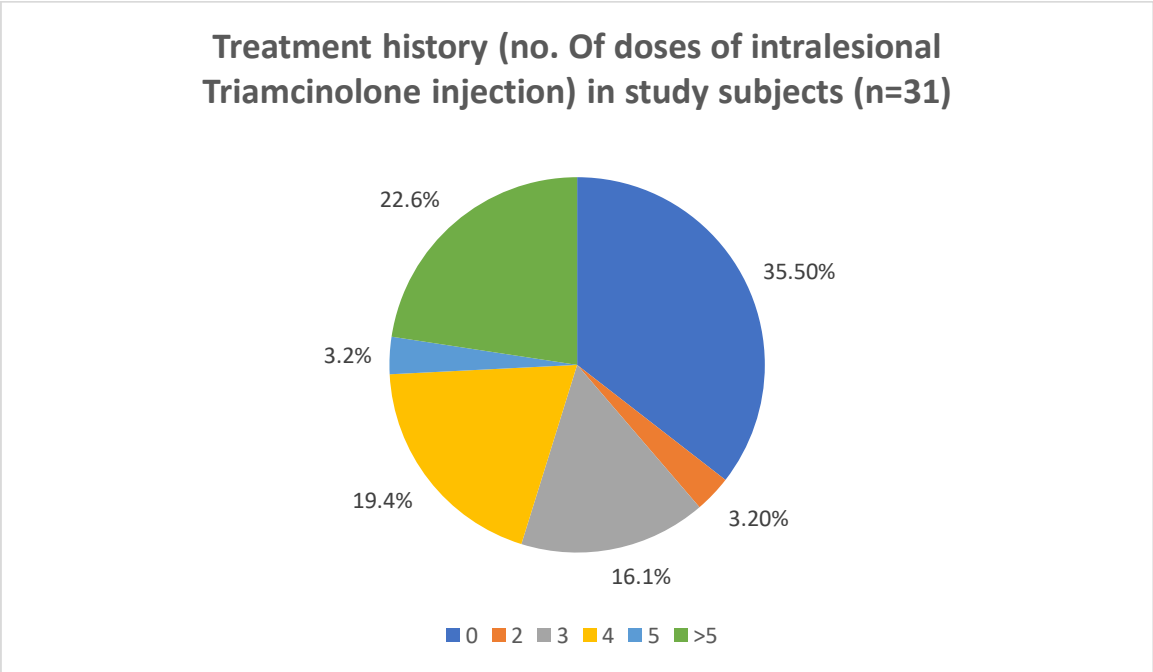


Fig 3: Treatment history

History of surgical excision:

In our research, 27 patients enrolled had no history of surgical excision, which accounted for 87.1% of the patients, while 4 patients (12.9%) had a history of presternal keloid excision 1-3 years ago, as described in Table 4 and Figure 4.

Table 4: History of surgical excision in study subjects (n=31)

History of surgical excision	No.	%
No	27	87.1
Yes	4	12.9

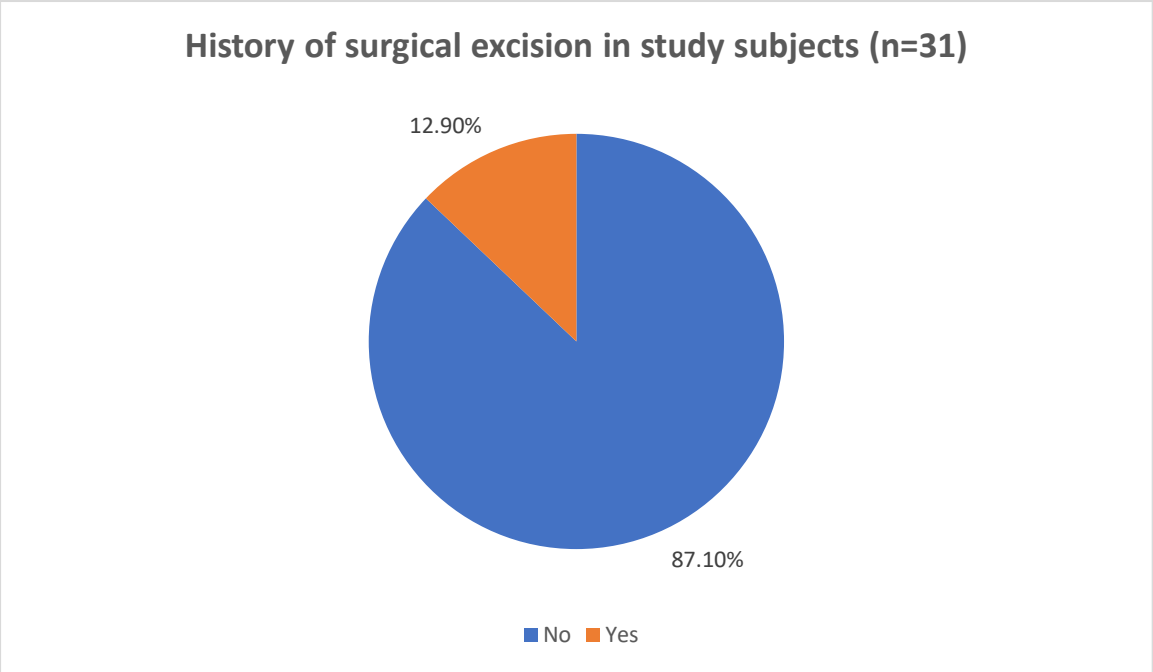


Fig 4: History of surgical excision

Symptoms:

In our study, itching was a predominant complaint, seen in 15 (48.4%) cases. Itching and burning sensation were noted in 8 (25.8%) cases. One (3.2%) patient had pus discharge alone, and 6 (19.4%) patients complained of itching and pus discharge - Table 5 and Fig 1.5.

Table 5: Associated symptoms in study subjects (n=31)

Associated symptoms	No.	%
Itching	15	48.4
Itching, burning sensation	8	25.8
Itching, pus discharge	6	19.4
Pus discharge	1	3.2

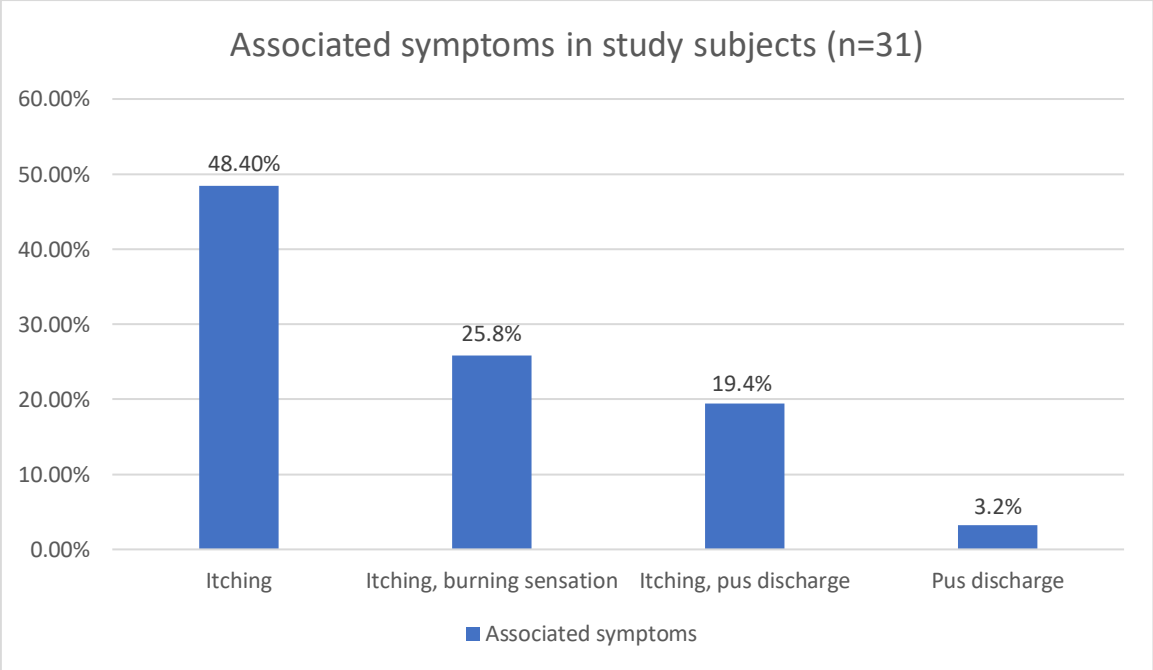


Fig 5: Associated symptoms

Size of presternal keloid:

The size of the presternal keloid is demonstrated in Table 6 and Fig 6. The mean size of the presternal keloid was 4.01 cm and 2.16 cm in horizontal and vertical dimensions, with standard deviations of 2.69 and 1.09, respectively. The minimum size was 1x1cm, and maximum size was 14x5cm.

Table 6: Size of presternal keloid in study subjects (n=31)

	Size of presternal keloid (maximum horizontal size in cm)	Size of presternal keloid (maximum vertical size in cm)
Mean	4.01	2.16
SD	2.69	1.09
Median	4.00	2.00
IQR	2-5	1-3
Minimum	1.0	1.0
Maximum	14.0	5.0

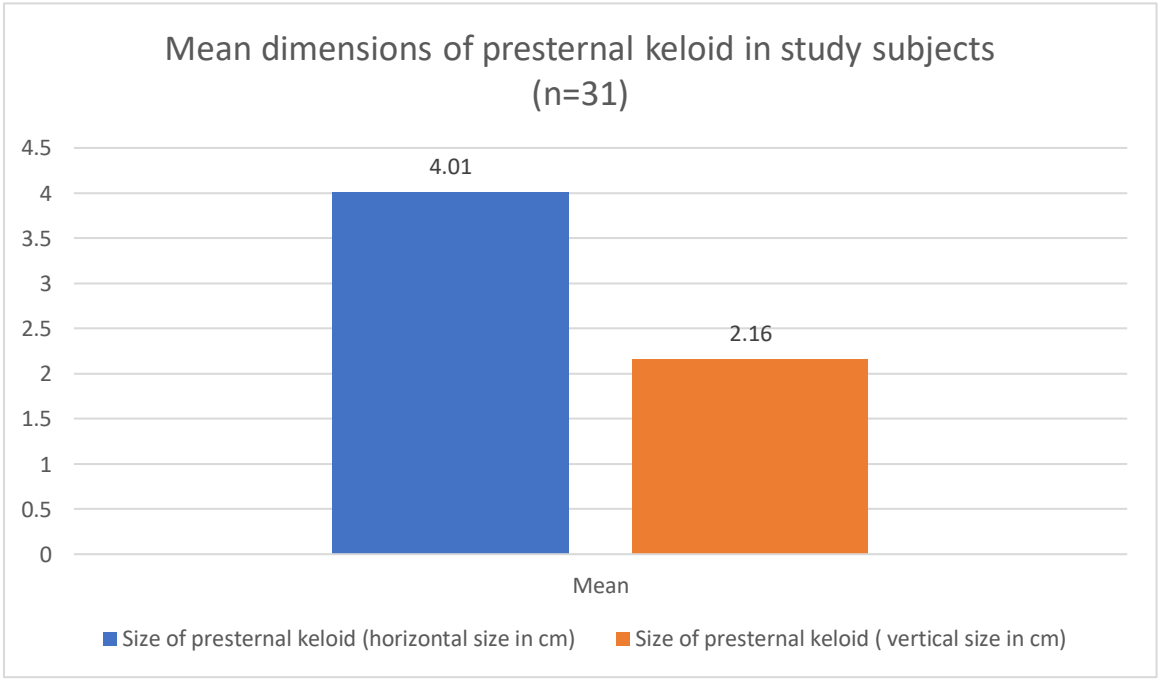


Fig 6: Size of presternal keloid

Surgical site description:

The mean size of the defect after presternal keloid excision was found to be 5.16cm and 3.27cm in horizontal and vertical dimensions. Maximum size of skin defect was 16.5cm x 7cm and minimum size was 1.5cm x 1.5cm. (Table 7, Fig 7)

Table 7: Defect size after excision in study subjects (n=31)

	Defect size after excision (maximum horizontal size in cm)	Defect size after excision (maximum vertical size in cm)
Mean	5.168	3.274
Std. Deviation	3.18	1.29
Median	4.000	3.0
IQR	3-6	2-4
Minimum	1.5	1.5
Maximum	16.5	7.0

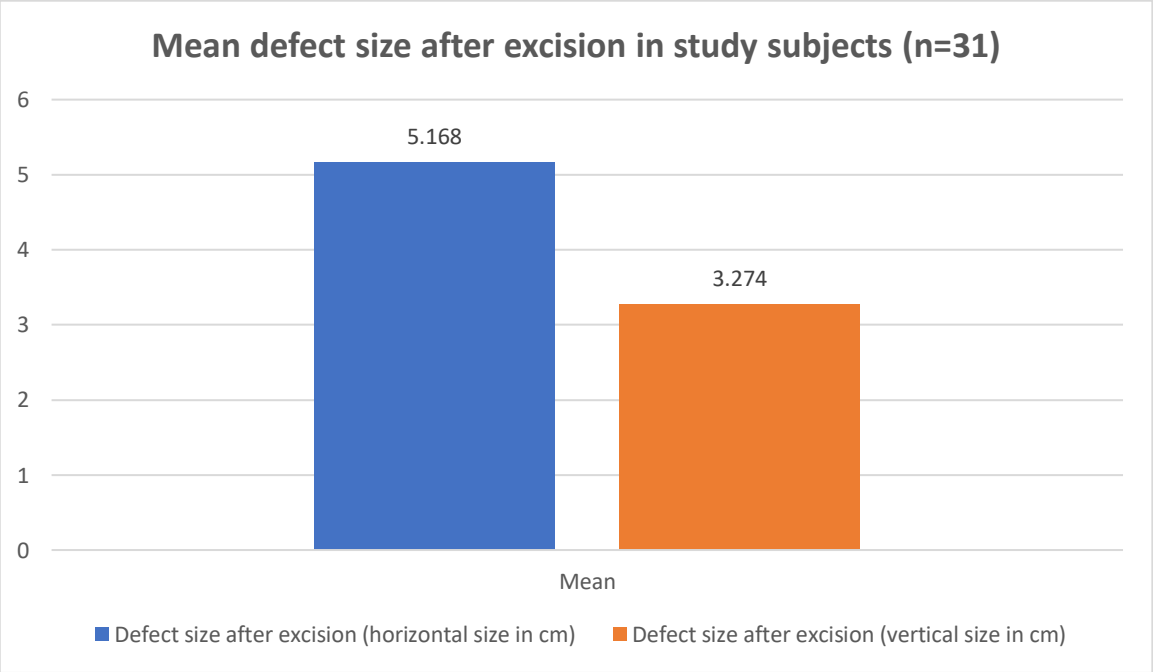


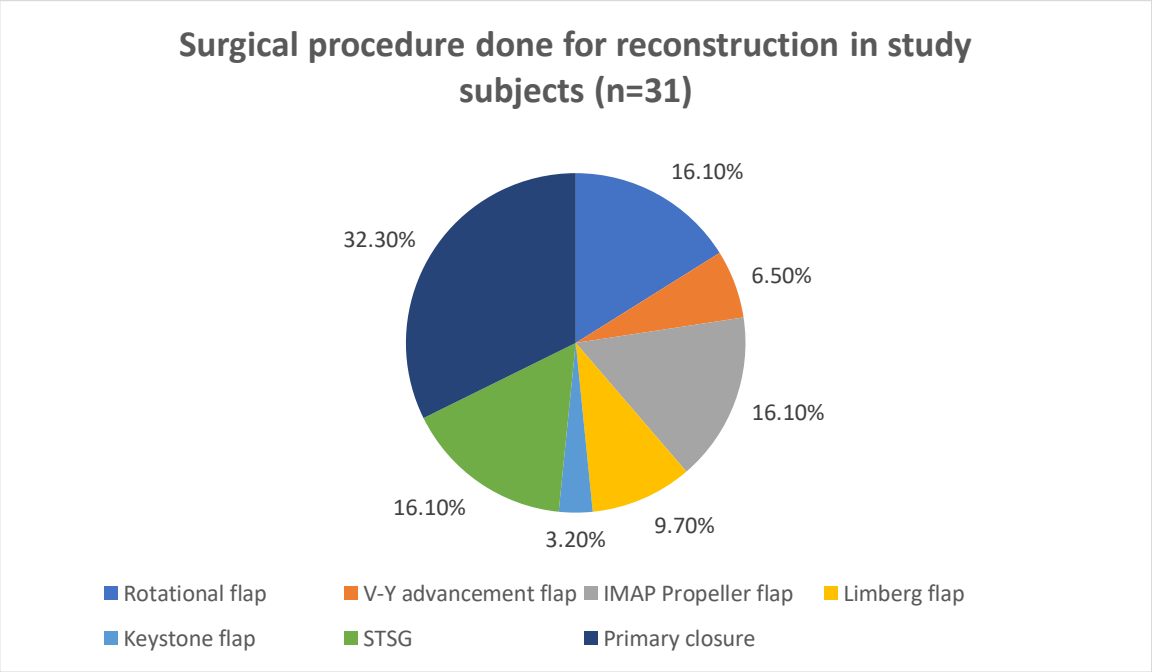
Fig 7: Size of the defect after presternal keloid excision

Defect reconstruction after presternal keloid excision:

After the excision of presternal keloids, the defects were closed primarily in 10 patients (32.3%). STSG was done in five (19.4%) of the patients. Locoregional flaps were used for resurfacing in 16 (48.4%) patients, as shown in Table 8 and Fig 8 below.

Table 8: Surgical procedure done in study subjects (n=31)

Procedure performed	No.	%
Rotational flap	5	16.1
V-Y advancement flap	2	6.5
Intercostal artery perforator-based propeller flap	5	16.1
Limberg flap	3	9.7
Keystone flap	1	3.2
STSG	5	16.1
Primary closure	10	32.3



Defect reconstruction after excision- Fig 8

Postoperative complications:

There were no complications in 23 (74.2%) patients. The following complications occurred in the study patients in the postoperative period: (Table 9, Fig 9)

- partial graft loss with hematoma in one patient (3.2%),
- wound dehiscence at two weeks in 1 (4.76%), and
- scar hypertrophy at 1-month post-op were noted in 6 (19.4%) patients.

Table 9: Postoperative complications in study subjects (n=31)

Postop complications	No.	%
Nil	23	74.2
Scar hypertrophy at one month	6	19.4
Wound dehiscence at two weeks	1	3.2
Hematoma with partial graft loss	1	3.2

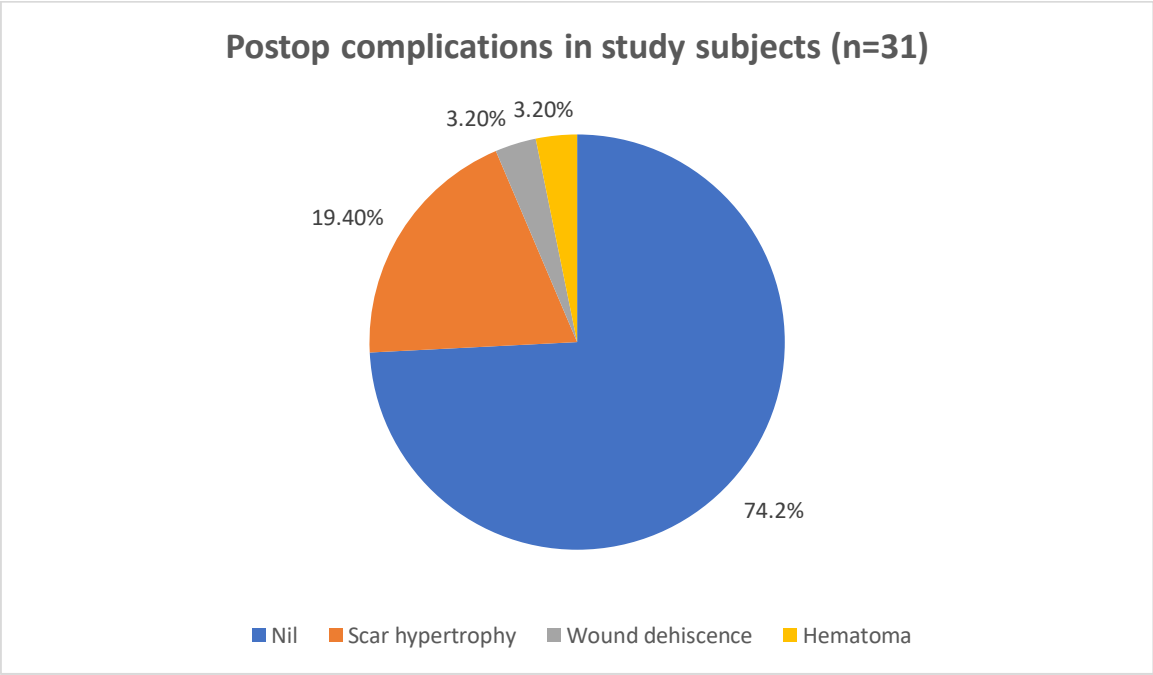


Table 9: Postoperative complications

Adjuvant therapy:

After the presternal keloids were excised and reconstructed, the patients were given the option to choose adjuvant therapy after explaining the advantages and complications of each. Radiation was opted for by two patients (6.5%) among them. Most patients (41.9%) chose silicone gel massage over suture line after suture removal as adjuvant therapy. 8 (25.80%) cases were given Triamcinolone injections.

Table 10: Adjuvant therapy postop in study subjects (n=31)

Adjuvant therapy postop	No.	%
Triamcinolone injection	8	25.80
Silicone gel massage over suture lines	13	41.9
silicone sheet application	8	25.80
Radiation	2	6.5

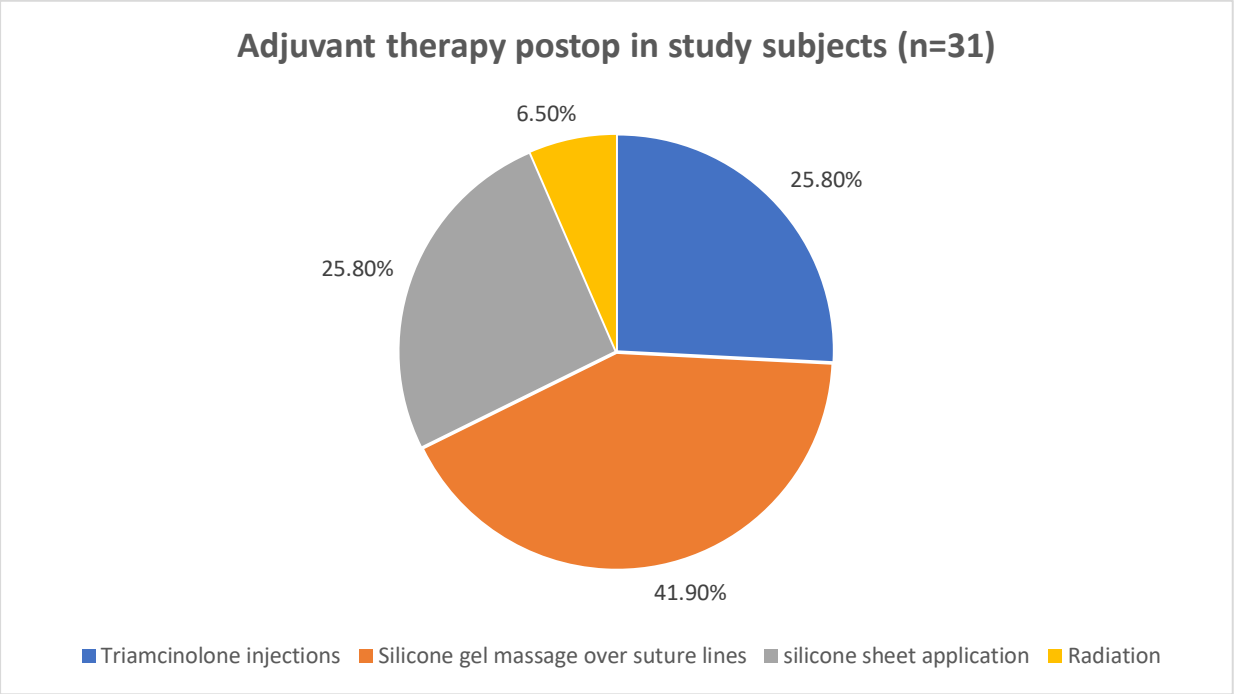


Fig 10: Adjuvant therapy postop

Likert's Scale:

The aesthetic outcome was evaluated using the Likert scale. Preoperative scores for 16 cases in the study were 1, and 15 patients scored 2. On assessment one year after surgery, 12 patients scored four on the Likert scale, demonstrating satisfaction with the aesthetic outcome. Two patients gave a score of 1 on the Likert scale at one-year post-op, demonstrating poor satisfaction with aesthetic outcomes after the surgery.

Overall, there was a significant improvement with regard to aesthetic outcome when comparing pre-operative values to one-year post-operative values. This denoted that the patients were satisfied with the post-operative aesthetic outcomes (p value< 0.001). The mean pre-operative Likert score was 1.48. The mean one-year post-operative Likert score was 3.26. (Table 11, Fig 11)

Table 11: Comparison of the mean pre-operative and post-operative Likert's score

	Preop	One year post-op	p-value
Likert score	1.48±0.50	3.26±0.77	**<0.001**

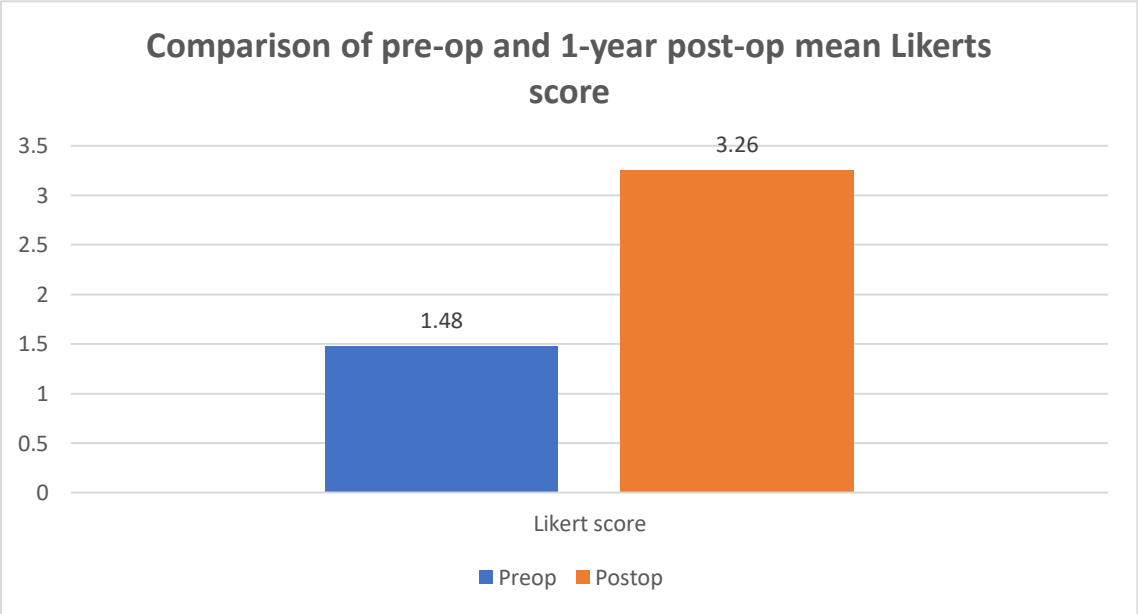


Fig 11: Likert's score pre-op and post-op

Scar Quality (POSAS PATIENT scale):

In our study, the outcomes were assessed after the treatment for all the patients one year post-operatively using POSAS (Patient and Observer Scar Assessment Scale). The mean pre-operative and 1-year post-operative scores were calculated. On analyzing the results, it was found that there was a significant improvement in the 1-year post-operative scores compared to the pre-operative scores on the POSAS patient scale (Intragroup p value< 0.001). The scale compared pain, itching, color, stiffness, thickness, and surface irregularity.

The mean value of overall patient opinion improved from 6.32 to 3.10. The average mean of the POSAS patient score improved from 26.81 to 11.90. Hence, the difference between the groups at the one-year post-operative period was statistically significant, as demonstrated in Table 12, Figure 12.

Table 12: Comparison of preop and postop POSAS patient scores

	Pre-op	**1-year post-op**	**p-value**
Overall patient opinion	6.32±1.70	3.10±1.01	**<0.001**
POSAS patient score	26.81±10.60	11.90±3.93	**<0.001**
Pain	3.10±1.79	1.10±0.30	**<0.001**
Itching	5.45±2.33	2.0±0.77	**<0.001**
Color	3.81±1.68	1.74±0.81	**<0.001**
Stiffness	4.39±1.64	2.16±0.86	**<0.001**
Thickness	4.68±1.64	2.10±0.70	**<0.001**
Irregularity	5.13±2.27	2.71±1.46	**<0.001**

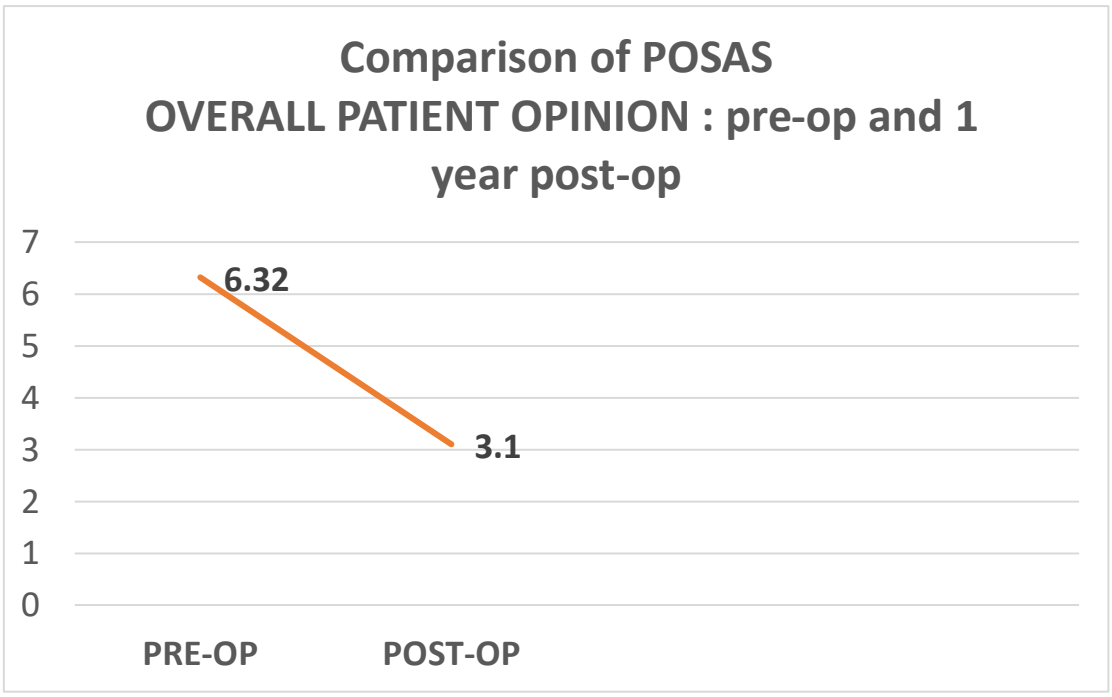


Fig 12.1: Comparison of POSAS OVERALL PATIENT OPINION pre-op and one-year post-surgery

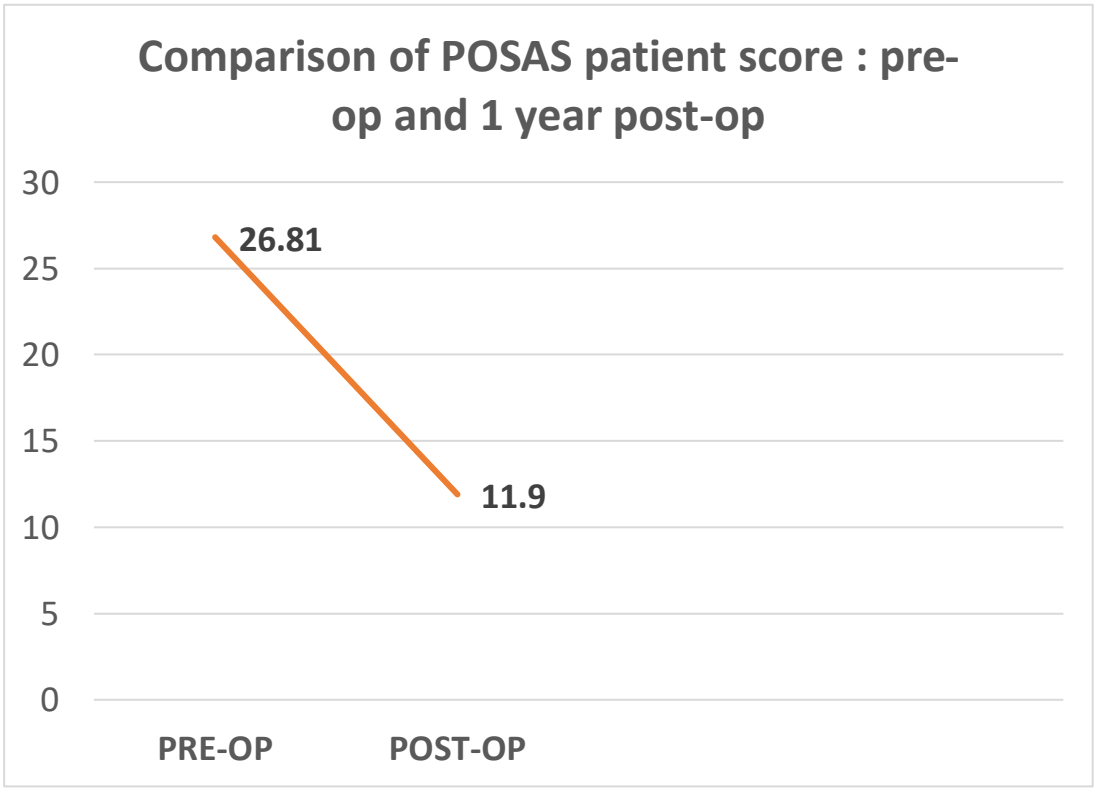


Fig 12.2: Comparison of POSAS patient score pre-op and one-year post-op

Pain:

The mean pre-operative pain score on the POSAS patient scale was 3.10 ± 1.79, and the mean one-year postoperative pain score was 1.10 ± 0.30. There was a statistically significant improvement in the mean postoperative pain score compared to the pre-operative score (p-value <0.001).

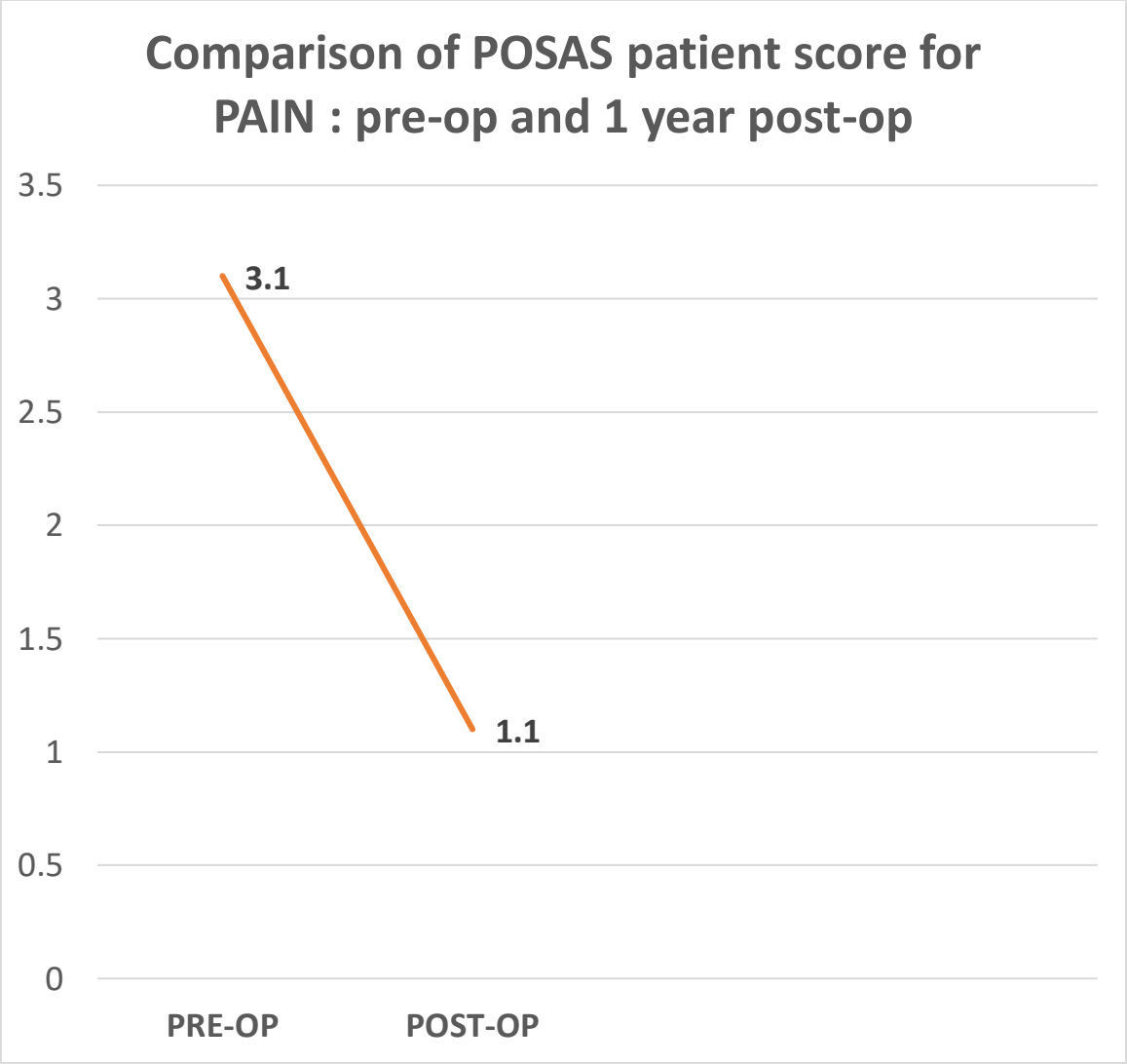


Fig 12.3: Comparison of POSAS patient score for PAIN: pre-op and 1-year post-op

Itching:

The mean pre-operative itching score on the POSAS patient scale was 5.45 ± 2.33, and the mean one-year postoperative itching score was 2.0 ± 0.77. There was a statistically significant improvement in the mean postoperative itching score compared to the pre-operative score (p-value <0.001).

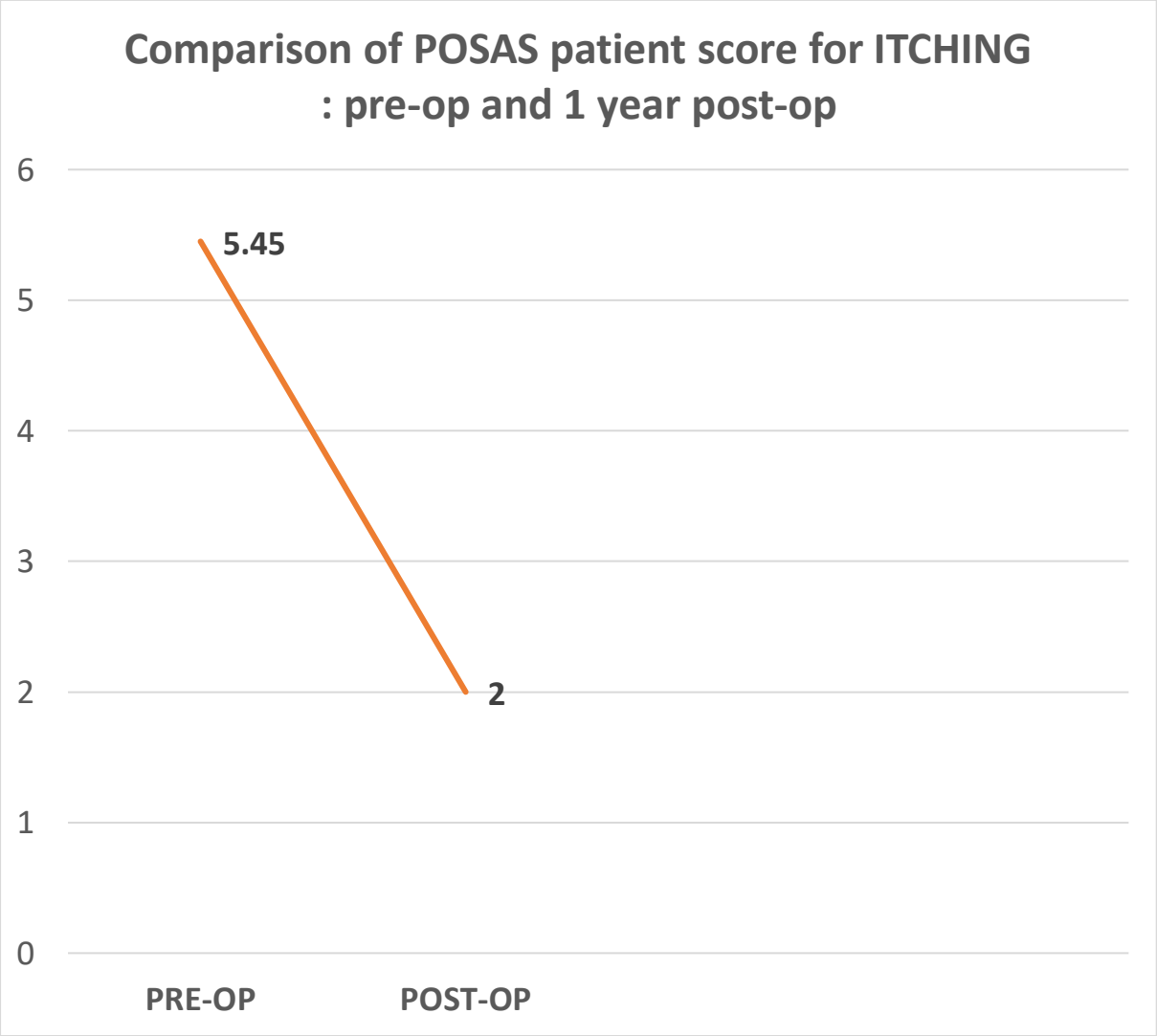


Fig 12.4: Comparison of POSAS patient score for ITCHING: pre-op and 1-year post-op

Colour:

The mean pre-operative color score on the POSAS patient scale was 3.81 ± 1.68, and the mean one-year postoperative color score was 1.74 ± 0.81. There was a statistically significant improvement in the mean postoperative color score compared to the pre-operative score (p-value <0.001).

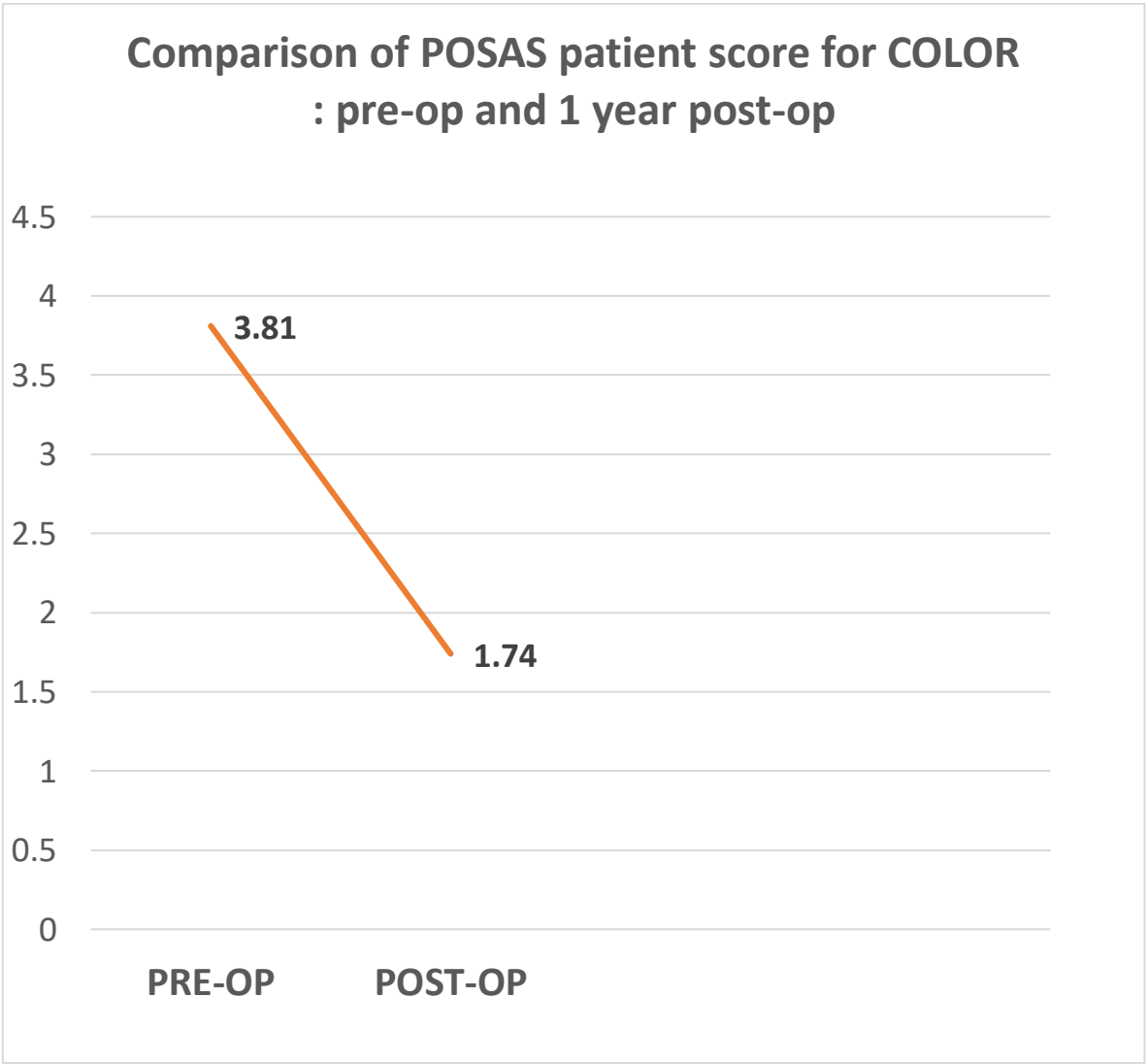


Fig 12.5: Comparison of POSAS patient score for COLOR: pre-op and 1-year post-op

Stiffness:

The mean pre-operative stiffness score on the POSAS patient scale was 4.39 ± 1.64, and the mean one-year postoperative stiffness score was 2.16 ± 0.86. There was a statistically significant improvement in the mean postoperative stiffness score compared to the pre-operative score (p-value <0.001).

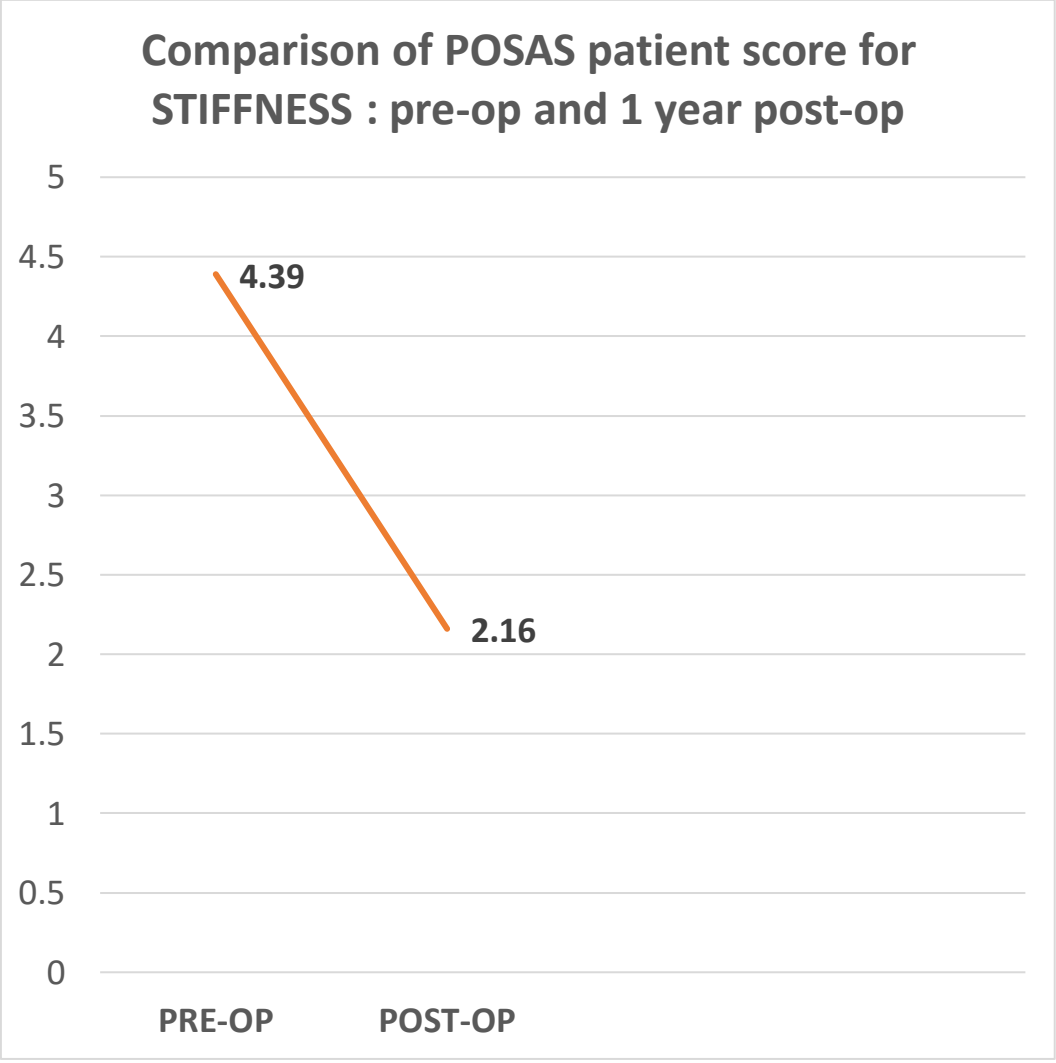


Fig 12.6: Comparison of POSAS patient score for STIFFNESS: pre-op and 1-year post-surgery

Thickness:

The mean pre-operative thickness score on the POSAS patient scale was 4.68 ± 2.27, and the mean one-year postoperative thickness score was 2.10 ± 0.70. There was a statistically significant improvement in the mean postoperative thickness score compared to the pre-operative score (p-value <0.001).

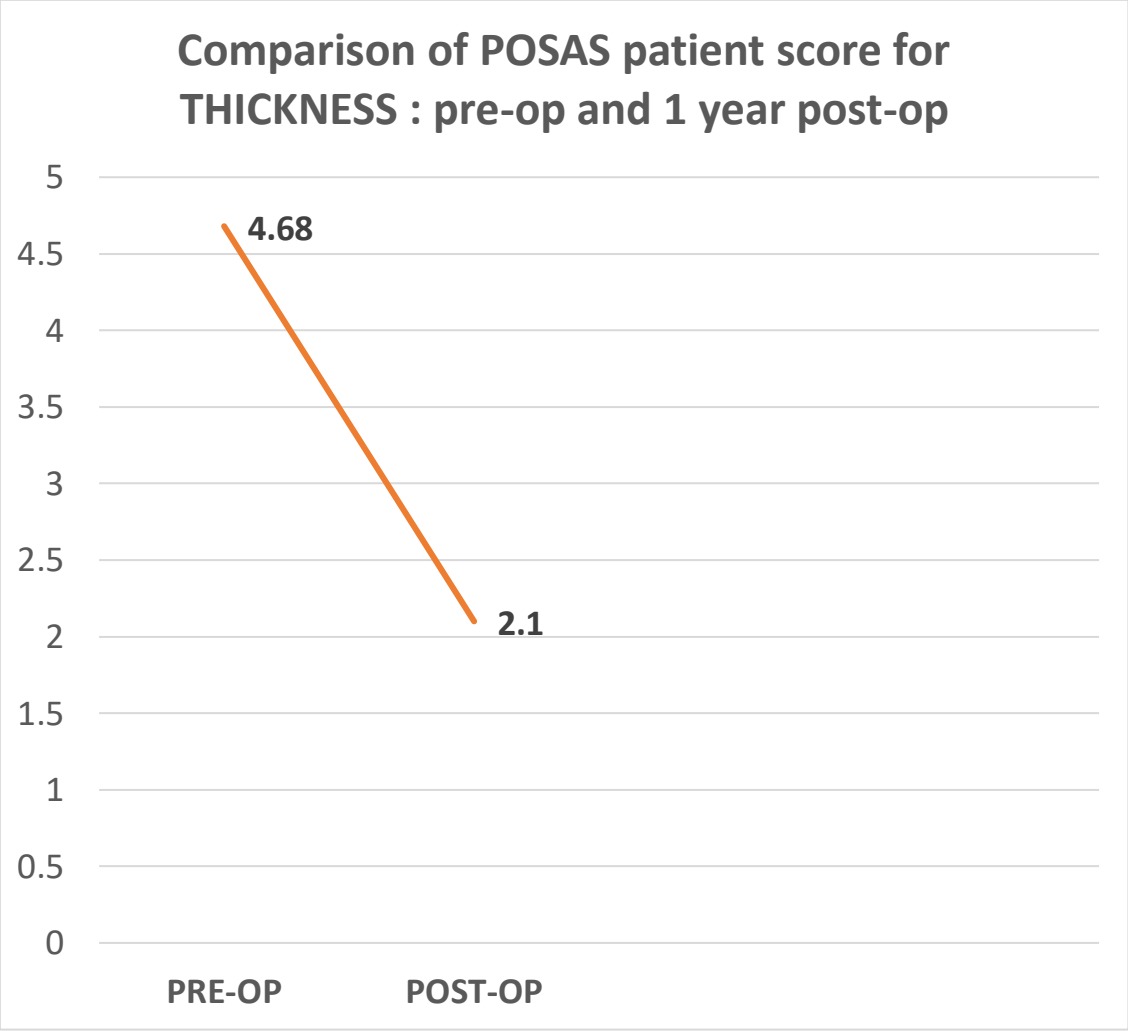


Fig 12.7: Comparison of POSAS patient score for THICKNESS: pre-op and 1-year post-surgery

Irregularity:

The mean pre-operative irregularity score on the POSAS patient scale was 5.13 ± 1.64, and the mean one-year postoperative irregularity score was 2.71 ± 1.46. There was a statistically significant improvement in the mean postoperative irregularity score compared to the pre-operative score (p-value <0.001).

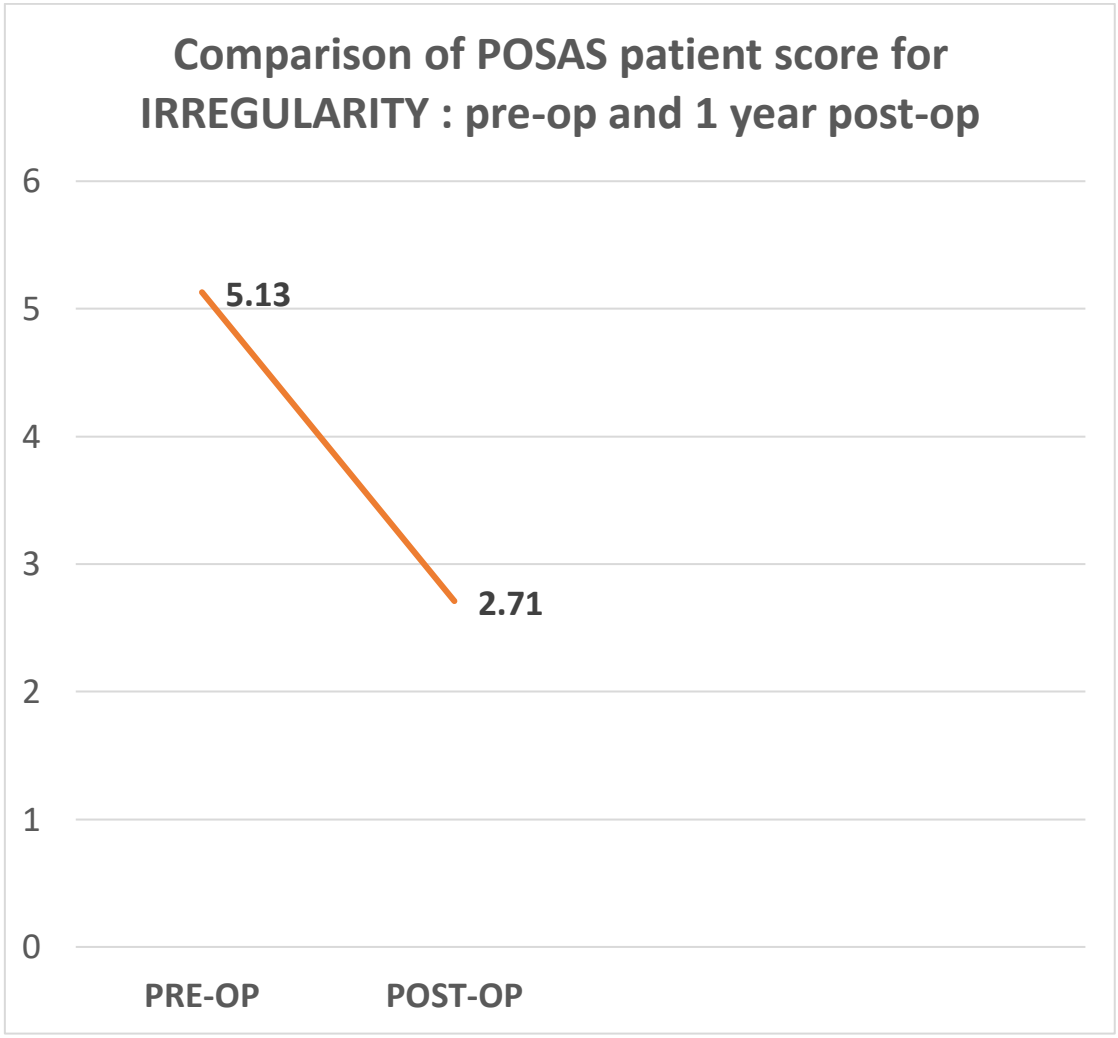


Fig 12.8: Comparison of POSAS patient score for IRREGULARITY: pre-op and 1-year post-surgery

Scar Quality (POSAS OBSERVER scale):

There was a significant improvement in scar quality comparing pre-operative to postoperative 1-year values per the observer's assessment (Intragroup p value< 0.001). The scale compared vascularity, pigmentation, thickness, relief, flexibility, and surface area.

The average mean for overall observer opinion improved from 5.94 to 3.23. The average mean of the POSAS observer score improved from 26.87 to 13.03. Hence, the difference between the groups at the one-year postoperative period was statistically significant. (Table 13, Figure 13)

Table 13: Comparison of observer score preop and postop

	Preop	**Postop**	**p-value**
Overall observer opinion	5.94±1.78	3.23±1.14	**<0.001**
POSAS observer score	26.87±9.68	13.03±4.65	**<0.001**
Vascularity	3.26±1.46	1.65±0.70	**<0.001**
Pigmentation	4.10±2.08	1.71±0.83	**<0.001**
Thickness	4.35±1.70	1.94±0.57	**<0.001**
Relief	4.84±2.05	2.39±1.17	**<0.001**
Pliability	4.94±2.04	2.35±0.89	**<0.001**
Surface area	5.71±2.16	3.0±1.59	**<0.001**

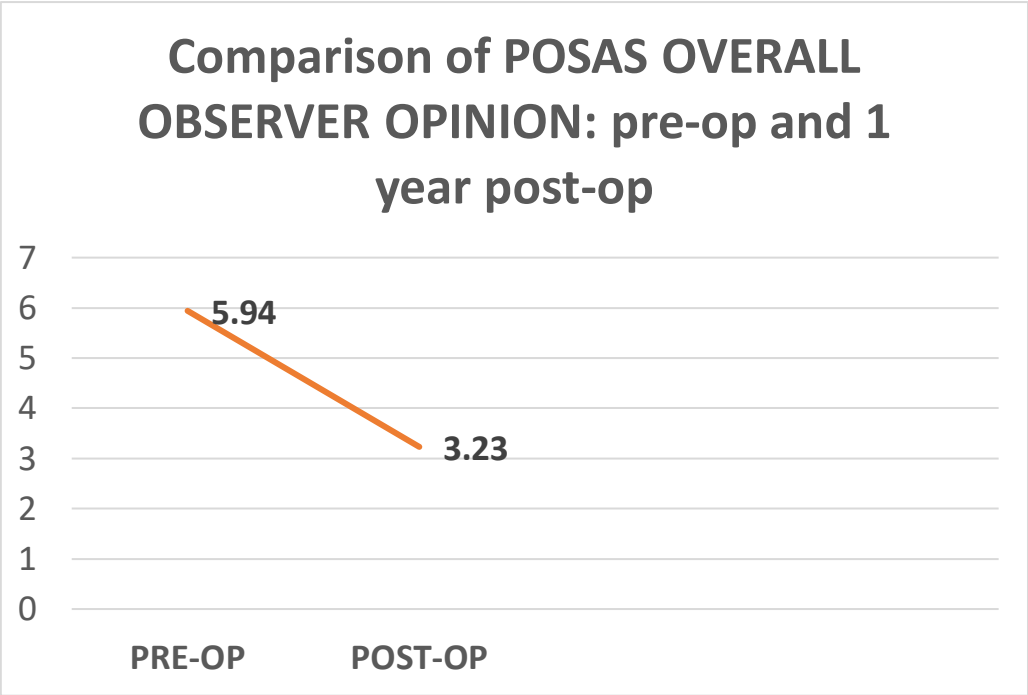


Fig 13.1: Comparison of POSAS OVERALL OBSERVER OPINION: pre-op and 1-year post-surgery

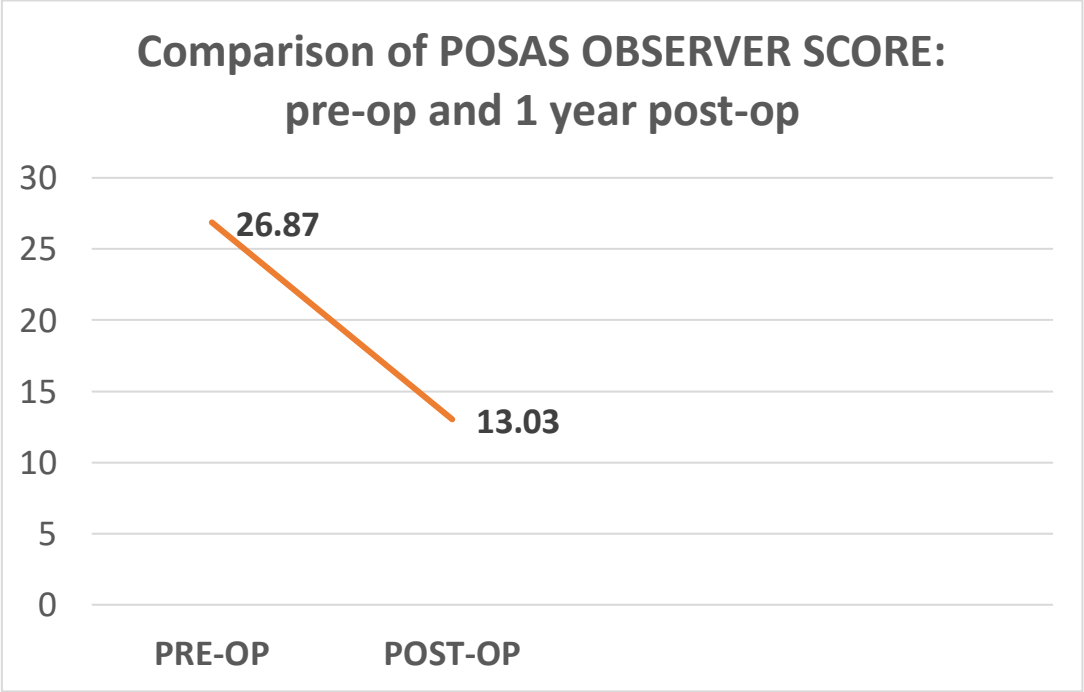


Fig 13.2: Comparison of POSAS OBSERVER SCORE: pre-op and 1-year post-surgery

Vascularity:

The mean pre-operative vascularity score in the POSAS observer scale was 3.26 ± 1.46, and the mean one-year postoperative vascularity score was 1.65 ± 0.70. There was a statistically significant improvement in the mean postoperative vascularity score compared to the pre-operative score (p-value <0.001).

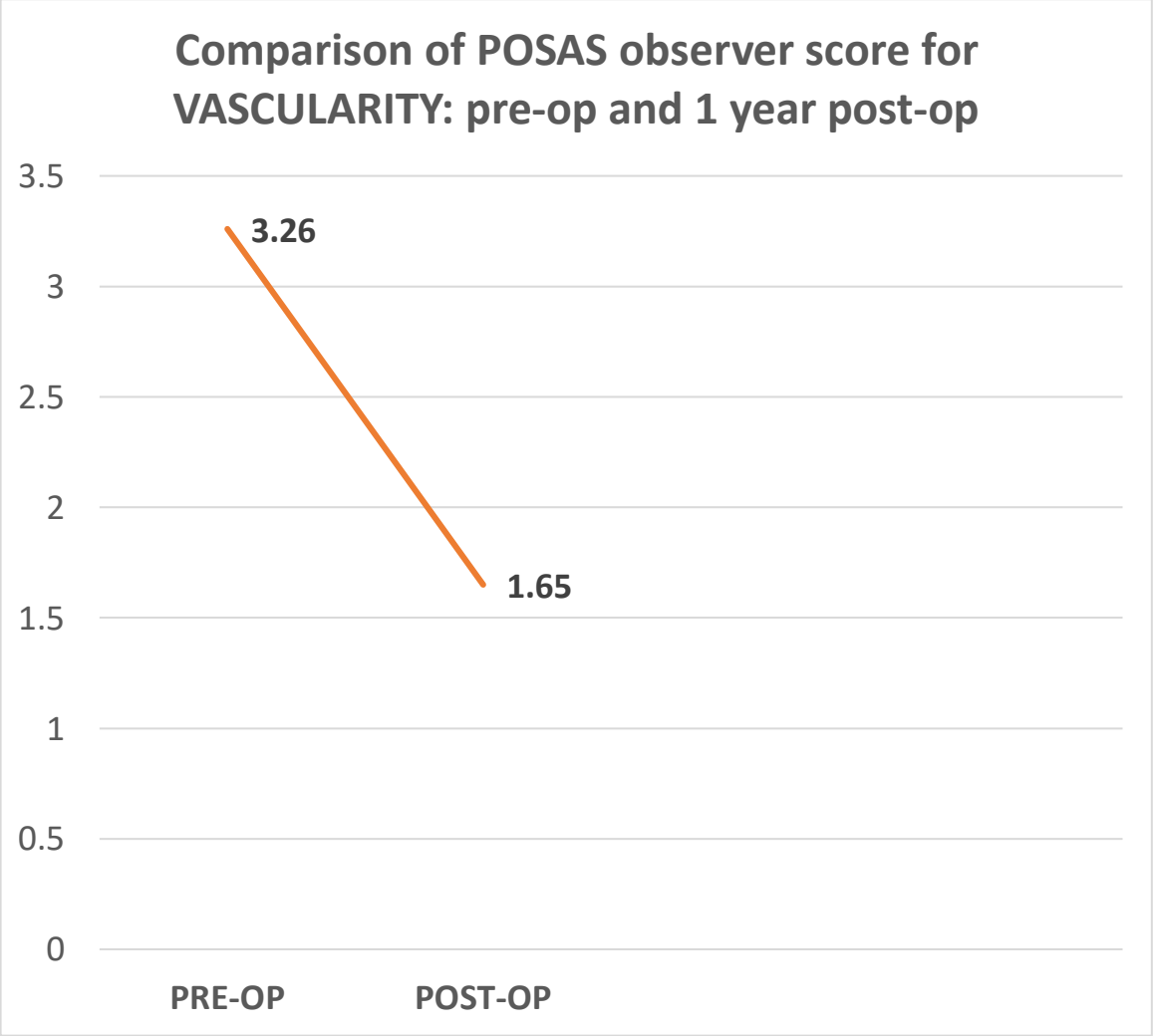


Fig 13.3: Comparison of POSAS observer score for VASCULARITY: pre-op and 1-year post-surgery

Pigmentation:

The mean pre-operative pigmentation score in the POSAS observer scale was 4.10 ± 2.08, and the mean one-year postoperative pigmentation score was 1.71 ± 0.83. There was a statistically significant improvement in the mean postoperative pigmentation score compared to the pre-operative score (p-value <0.001).

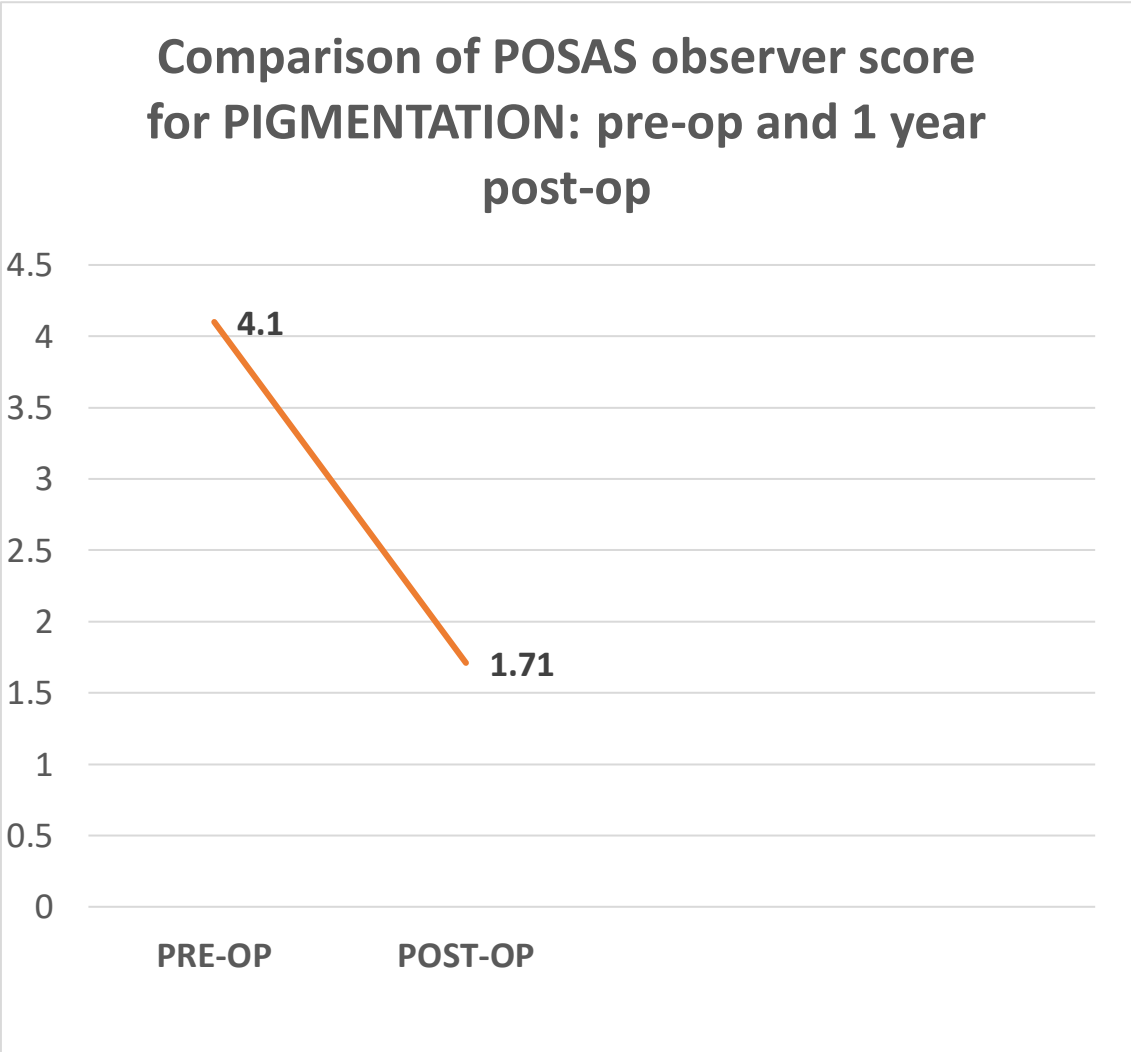


Fig 13.4: Comparison of POSAS observer score for PIGMENTATION: pre-op and one-year post-surgery

Thickness:

The mean pre-operative thickness score in the POSAS observer scale was 4.35 ± 1.70, and the mean one-year postoperative thickness score was 1.94 ± 0.57. There was a statistically significant improvement in the mean postoperative thickness score compared to the pre-operative score (p-value <0.001).

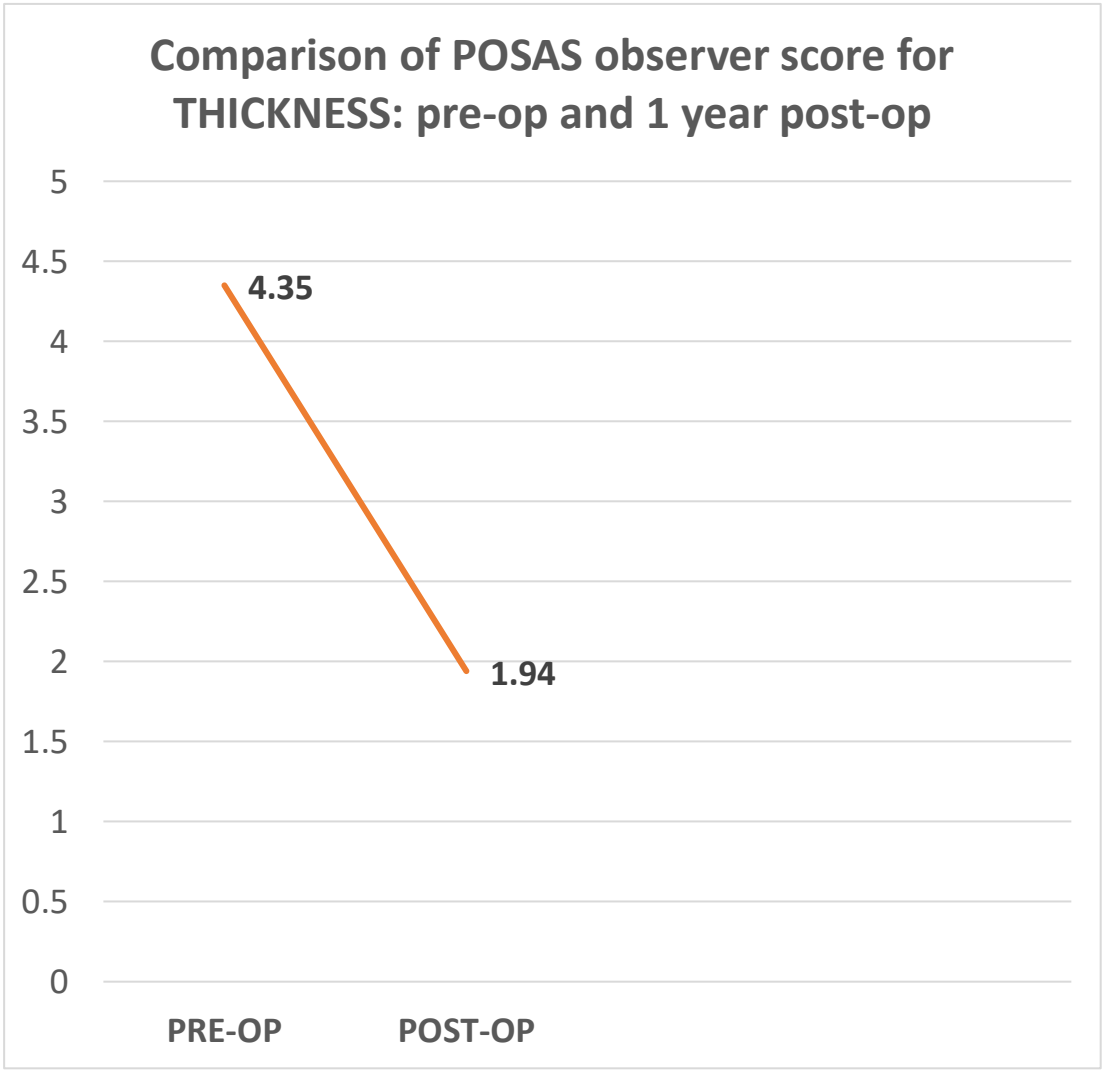


Fig 13.5: Comparison of POSAS observer score for THICKNESS: pre-op and one-year post-surgery

Relief:

The mean pre-operative relief score on the POSAS observer scale was 4.84 ± 2.05, and the mean one-year postoperative relief score was 2.39 ± 1.17. There was a statistically significant improvement in the mean postoperative relief score compared to the pre-operative score (p-value <0.001).

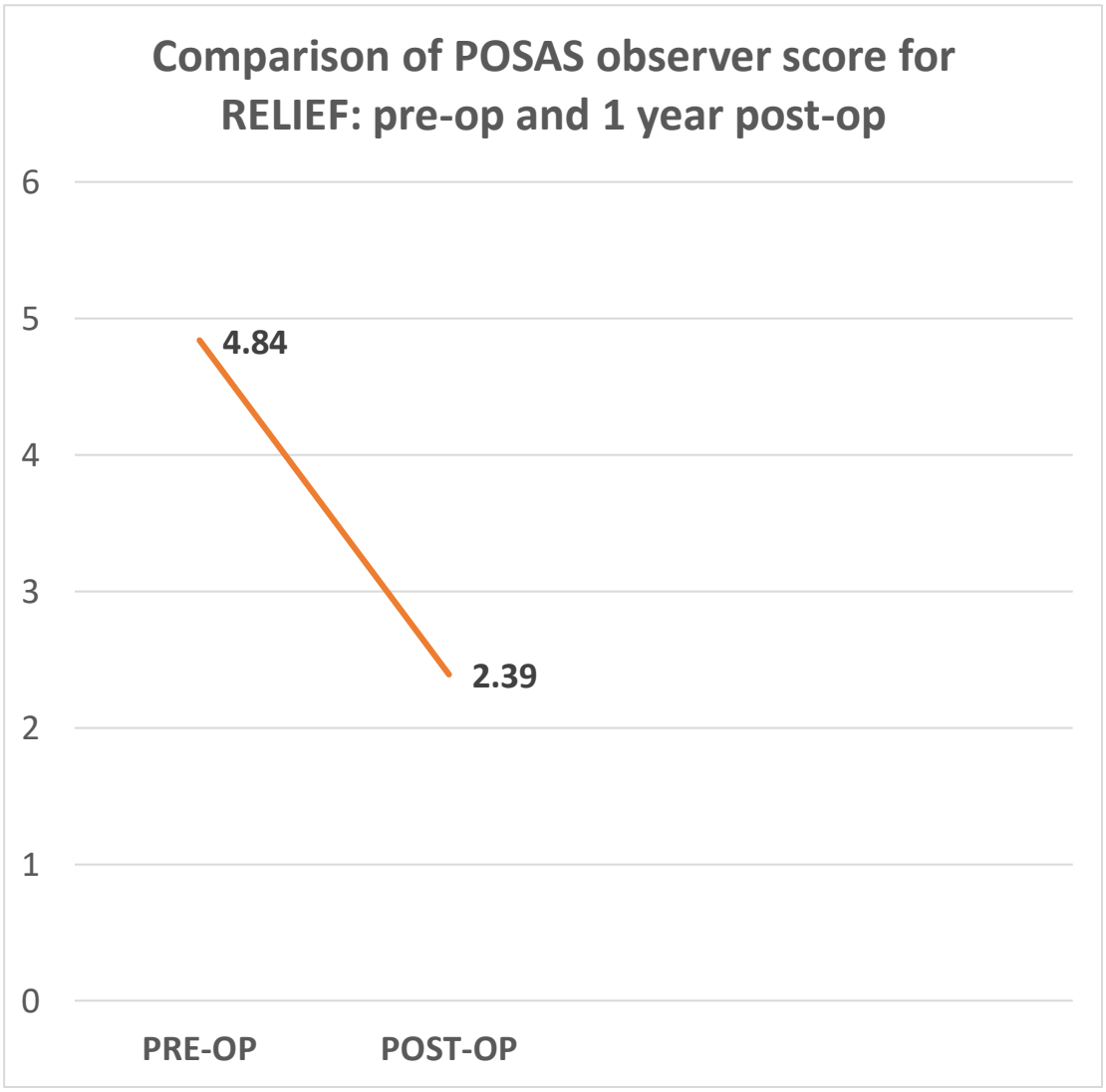


Fig 13.6: Comparison of POSAS observer score for RELIEF: pre-op and one-year post-surgery

Pliability:

The mean pre-operative pliability score in the POSAS observer scale was 4.94 ± 2.04, and the mean one-year postoperative pliability score was 2.35 ± 0.89. There was a statistically significant improvement in the mean postoperative pliability score compared to the pre-operative score (p-value <0.001).

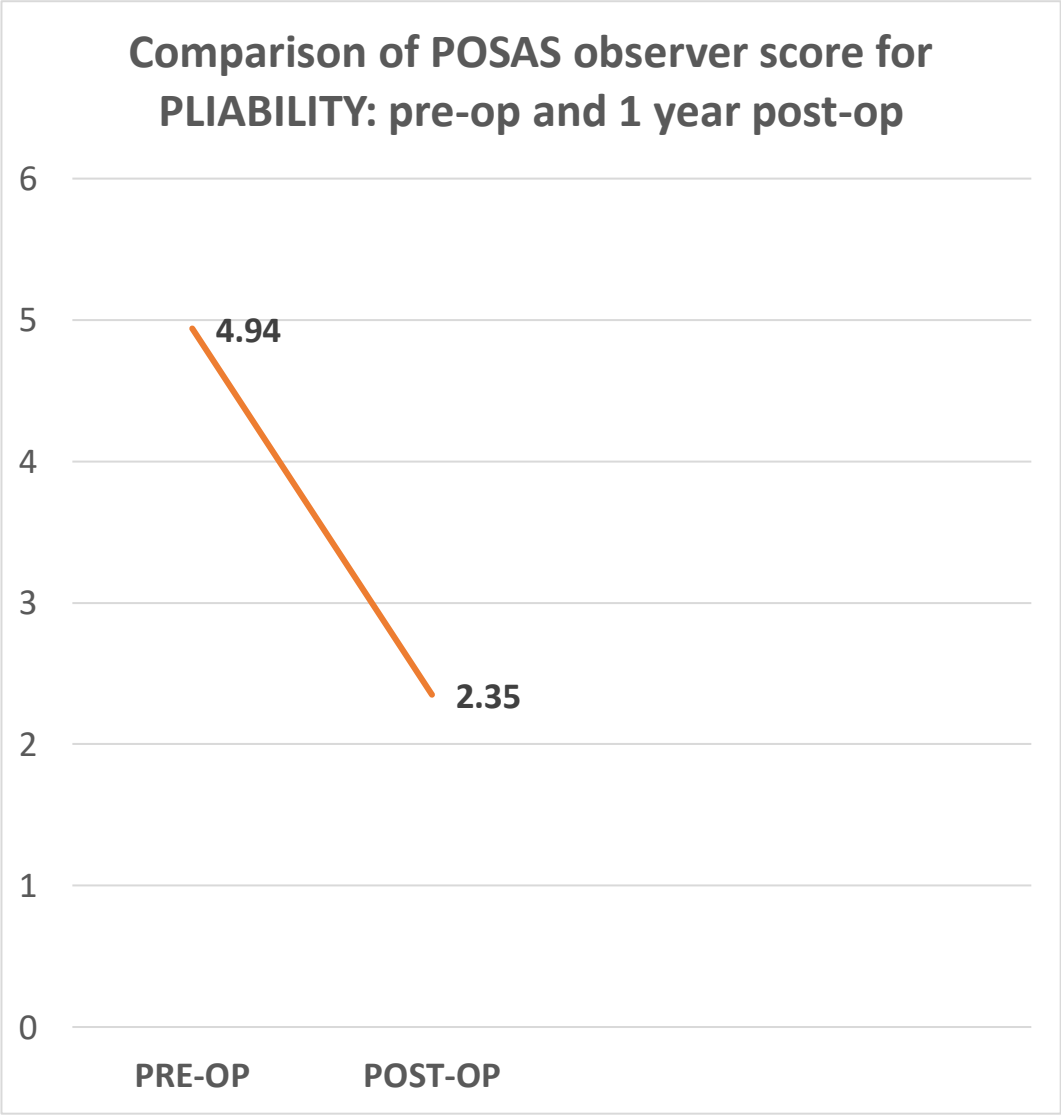


Fig 13.7: Comparison of POSAS observer score for PLIABILITY: pre-op and one-year post-surgery

Surface area:

The POSAS observer scale's mean pre-operative surface area score was 5.71 ± 2.16, and the mean one-year postoperative surface area score was 3.0 ± 1.59. There was a statistically significant improvement in the mean postoperative surface area score compared to the pre-operative score (p-value <0.001).

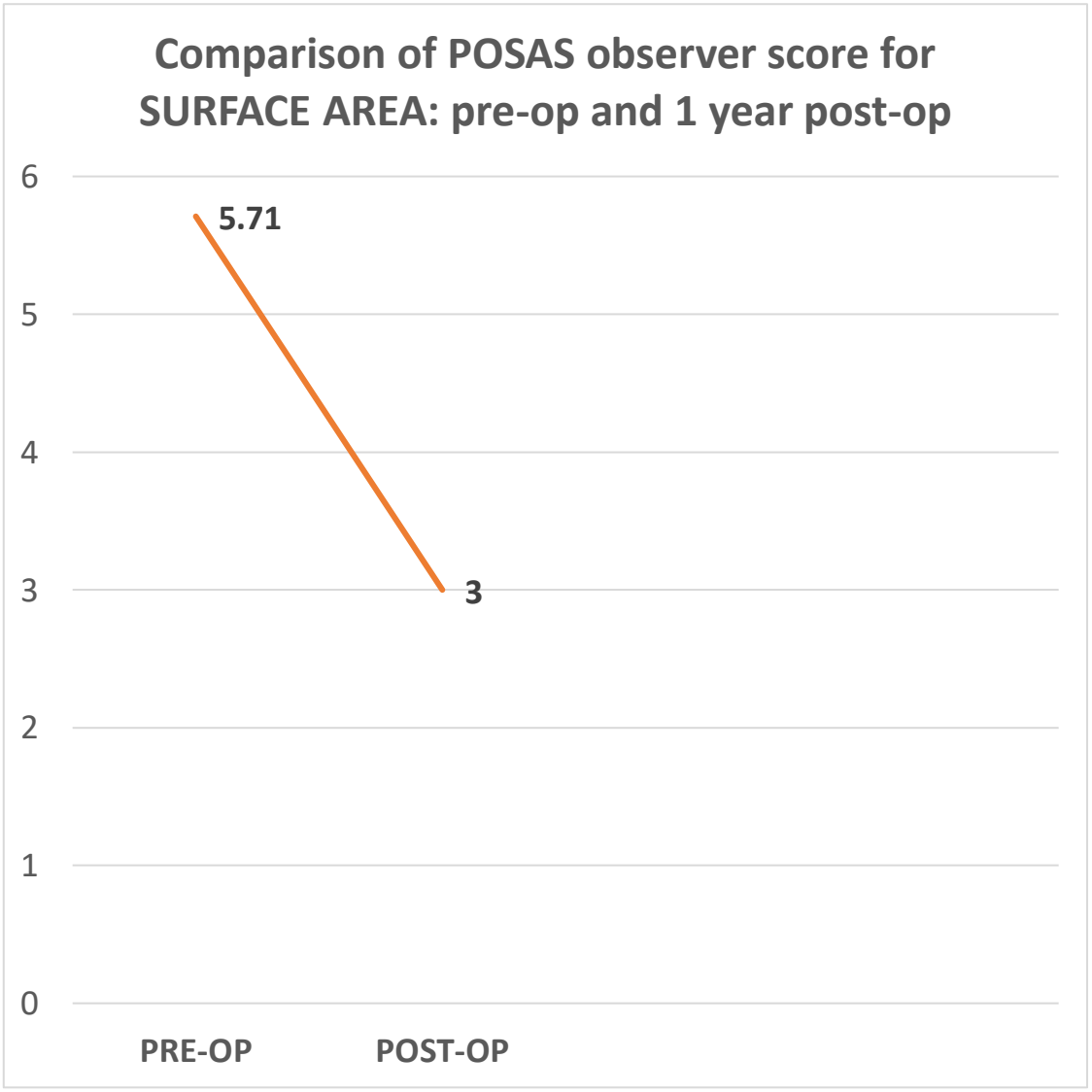


Fig 13.8: Comparison of POSAS observer score for PLIABILITY: pre-op and one-year post-surgery

Comparison of the pre-op and the post-op POSAS patient and observer scores for different types of surgical interventions: primary closure, local flaps, and split-thickness skin grafts-

There was no significant difference in the overall patient opinion in groups where different surgeries were done when comparing preoperative to one-year postoperative values. The intragroup p value was < 0.001, whereas the intergroup p value was 0.38 and 0.91 preoperatively to one year post-operatively. The average mean of overall patient opinion improved in all three groups- flaps, STSG, and primary closure in the 1-year postoperative period.

There was no significant difference in the overall observer opinion in groups where different surgeries were done when comparing preoperative to one-year postoperative values. The intragroup p value was < 0.001, whereas the intergroup p value was 0.53 and 0.41 preoperatively to one year post-operatively. The average mean of overall patient opinion improved in all three groups- flaps, STSG, and primary closure in the 1-year postoperative period. Hence, a statistically insignificant difference was observed in both overall patient and observer between the groups one year postoperatively.

The POSAS patient score, when compared preoperatively and one year postoperatively for flaps, STSG, and primary closure groups, were found to have significant intragroup p values <0.001 and insignificant intergroup p values 0.15 and 0.15, respectively.

The POSAS observer score, when compared preoperatively and one year postoperatively for flaps, STSG, and primary closure groups, were found to have significant intragroup p values <0.001 and insignificant intergroup p values 0.26 and 0.14, respectively.

In our study, the post-op POSAS patient and observer scores were worsened in three patients, and the incidence of recurrence was found to be 9.67%.

Table 14: Comparison of pre-op and post-op observer and patient scores in different types of surgeries

	Flaps	STSG	Primary closure	Intergroup p-value
Overall patient opinion				
Preop	6.73±1.28	6.17±1.47	5.80±2.30	0.38
Postop	3.13±0.99	3.17±0.98	3.0±1.15	0.91
Intragroup p value	**<0.001**	**<0.001**	**<0.001**	
POSAS patient score				
Preop	30.80±9.71	23.50±9.60	22.80±11.17	0.15
Postop	12.73±3.12	11.33±3.77	11.0±5.12	0.15
Intragroup p value	**<0.001**	**<0.001**	**<0.001**	
Overall observer opinion				
Preop	6.27±1.48	5.83±1.72	5.50±2.27	0.53
Postop	3.40±0.91	3.33±1.21	2.90±1.44	0.41
Intragroup p value	**<0.001**	**<0.001**	**<0.001**	
POSAS observer score				
Preop	29.67±9.02	25.83±8.70	23.30±10.77	0.26
Postop	14.07±4.04	13.0±4.56	11.50±5.54	0.14
Intragroup p value	**<0.001**	**<0.001**	**<0.001**	

Images

IMAGES

CASE 1

IMAGE 1: Pre-operative picture of presternal keloid

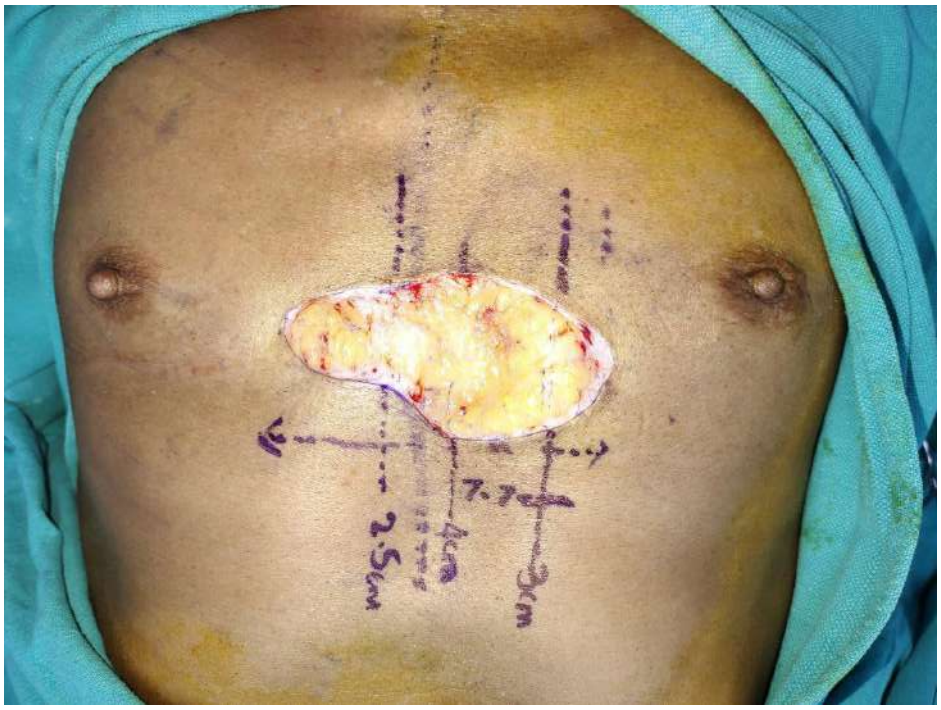


IMAGE 2: Defect after excision of presternal keloid

IMAGE 3: Excised specimen of the keloid

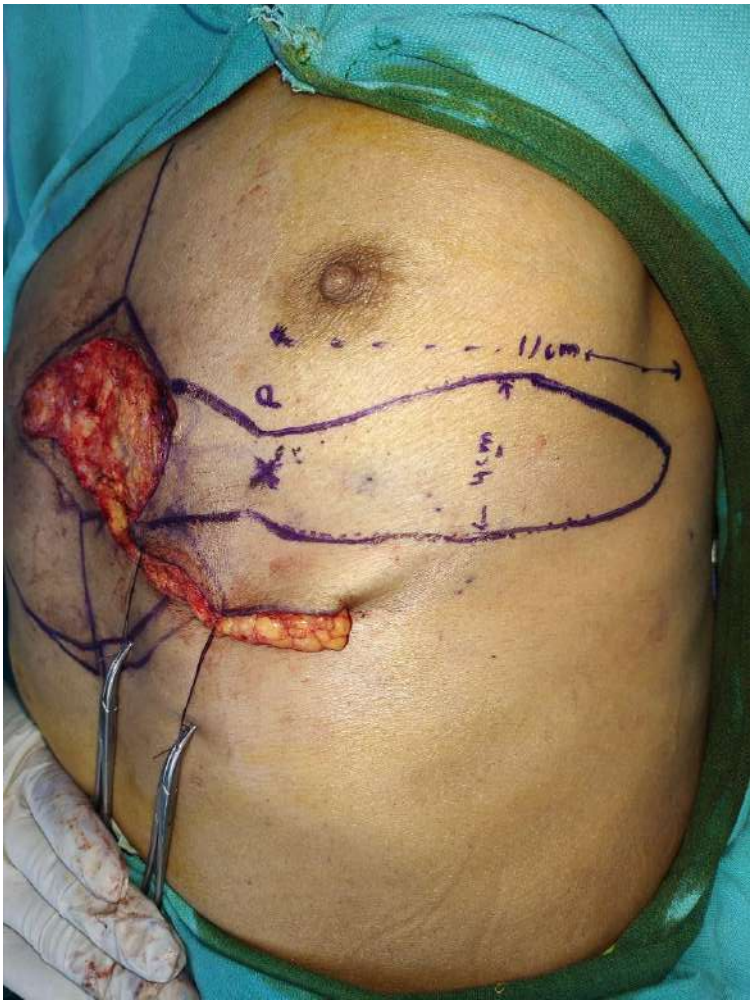


IMAGE 4: Marking of 4th intercoastal perforator flap

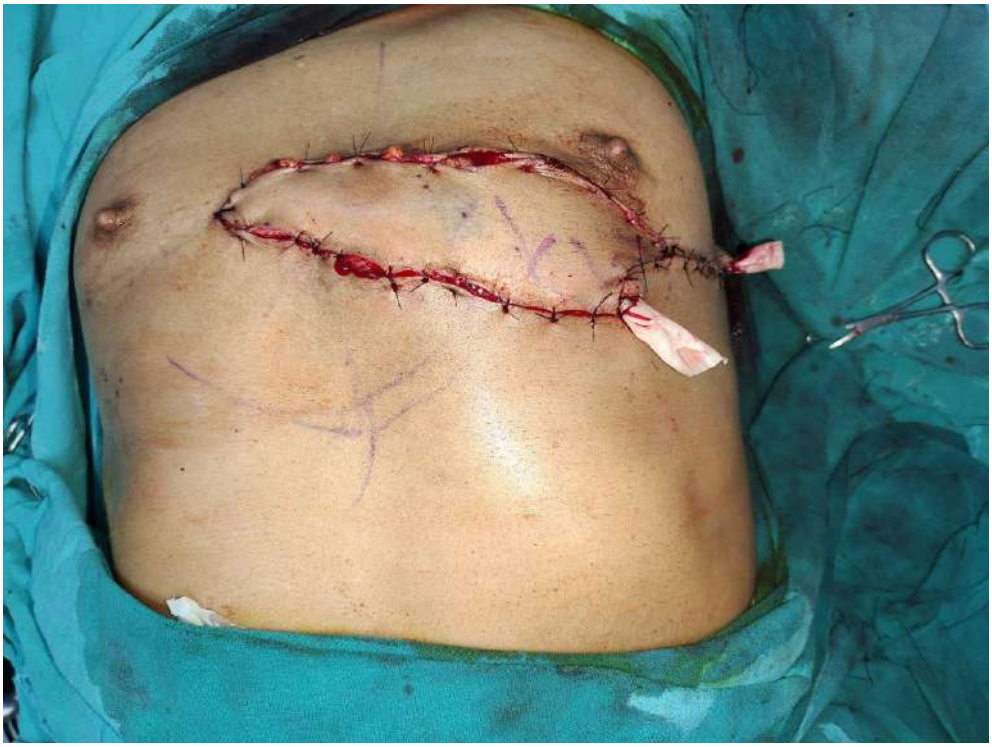


IMAGE 5: Intra-operative picture after 4th IMAP flap inset

IMAGE 6: Post-operative picture at 1 year follow-up after 4th IMAP flap cover after presternal keloid excision

CASE 2

IMAGE 7: Pre-operative picture of a patient with 2 presternal keloids

IMAGE 8: IMAP perforator marking using hand held doppler

IMAGE 9: Excised lesion and flap marking

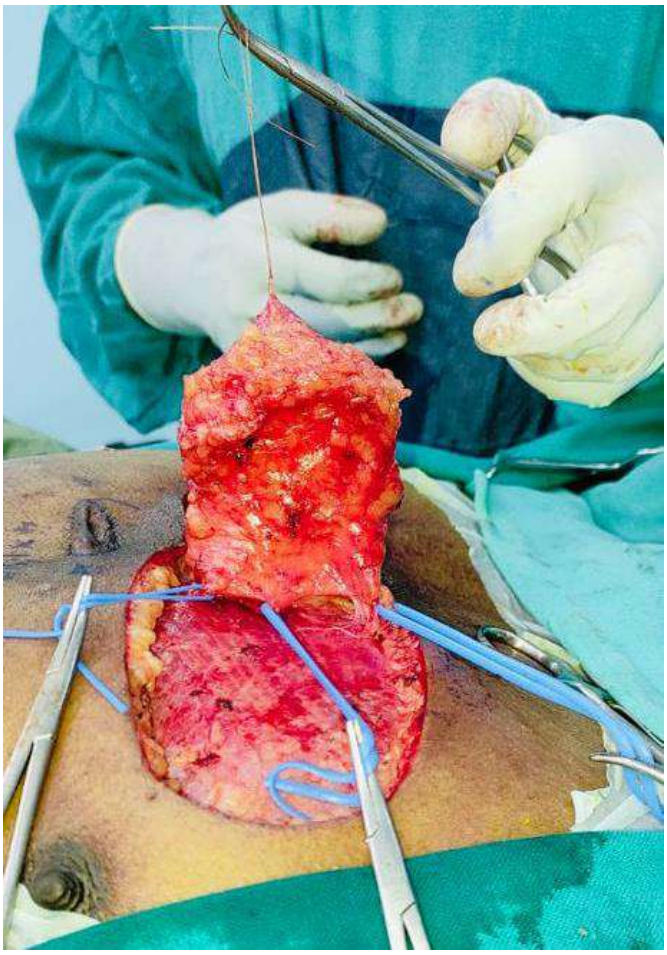


IMAGE 10: Intra-operative picture showing 2,3 IMAP perforators in vascular loops

IMAGE 11: Intra-operative picture after 2nd IMAP flap inset

IMAGE 12: Donor site wound dehiscence

IMAGE 13: Post-operative picture at 1 year follow-up with donor site scar hypertrophy

CASE 3

IMAGE 14: Pre-operative picture of butterfly shaped keloid

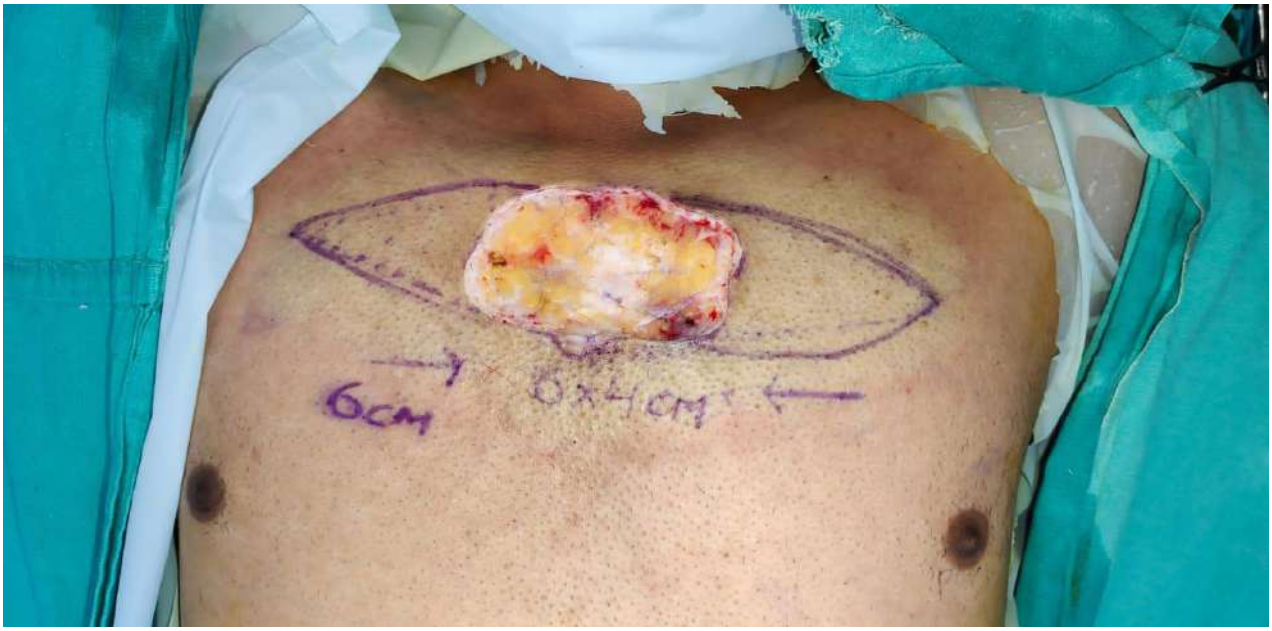


IMAGE 15: Defect and flap marking

IMAGE 16: Intra-op: Harvested bilateral V-Y advancement flap for defect cover

IMAGE 17: Intra-op picture after flap inset

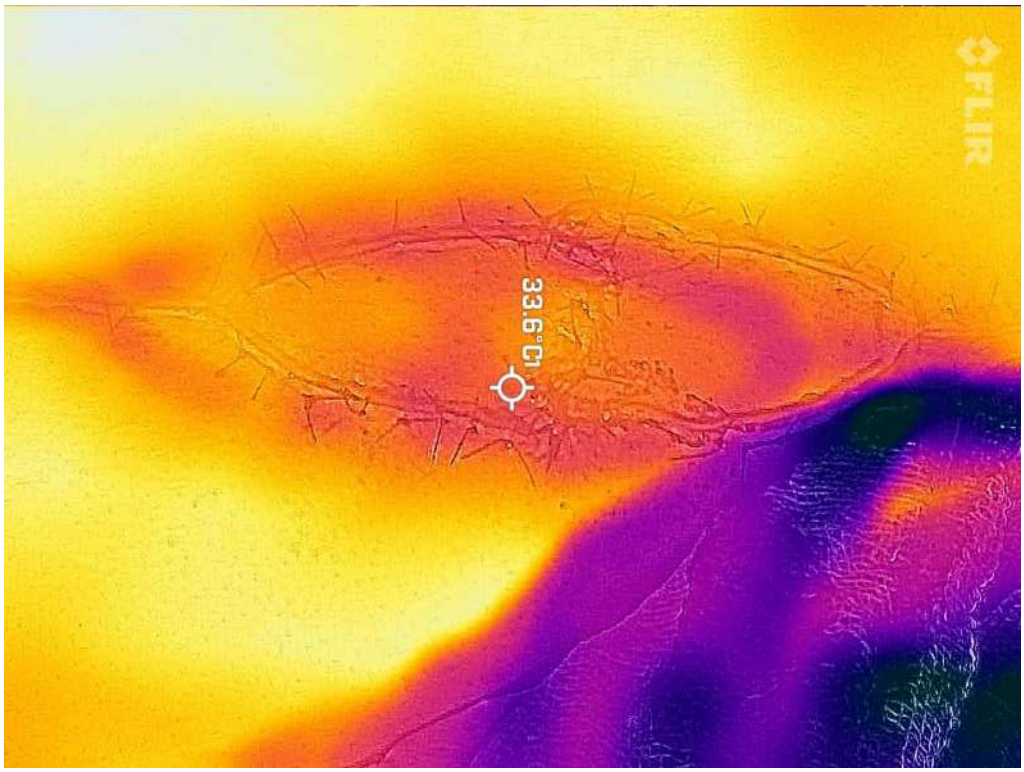


IMAGE 18: Flap monitoring using infrared camera

IMAGE 19: Post-operative picture at 1 year follow-up after B/L V-Y advancement flap cover after presternal keloid excision

Case 4

IMAGE 20: Pre-operative picture of dumbell shaped keloid

IMAGE 21: keystone flap marking after measuring the defect

IMAGE 22: Intra-op picture after keystone flap inset

IMAGE 23: Post-operative picture at 1 year follow-up after Keystone flap cover after presternal keloid excision

Case 5

IMAGE 24: Pre-operative picture of presternal keloid in a hairy-chested male patient

IMAGE 25: Post-operative picture at 1-year follow-up after presternal keloid excision and B/L rotation flap cover

Case 6

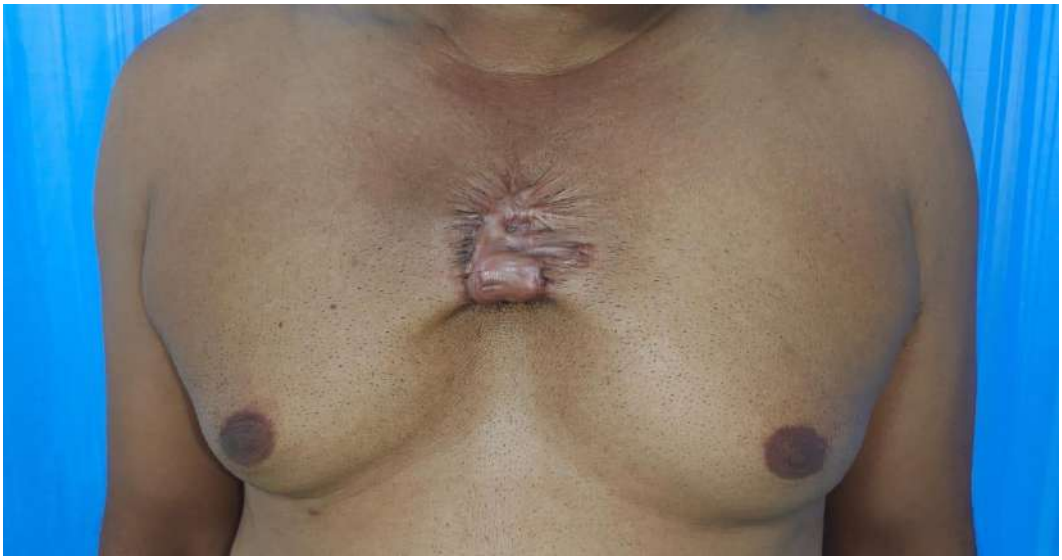


IMAGE 26: Pre-operative picture of pear-shaped presternal keloid

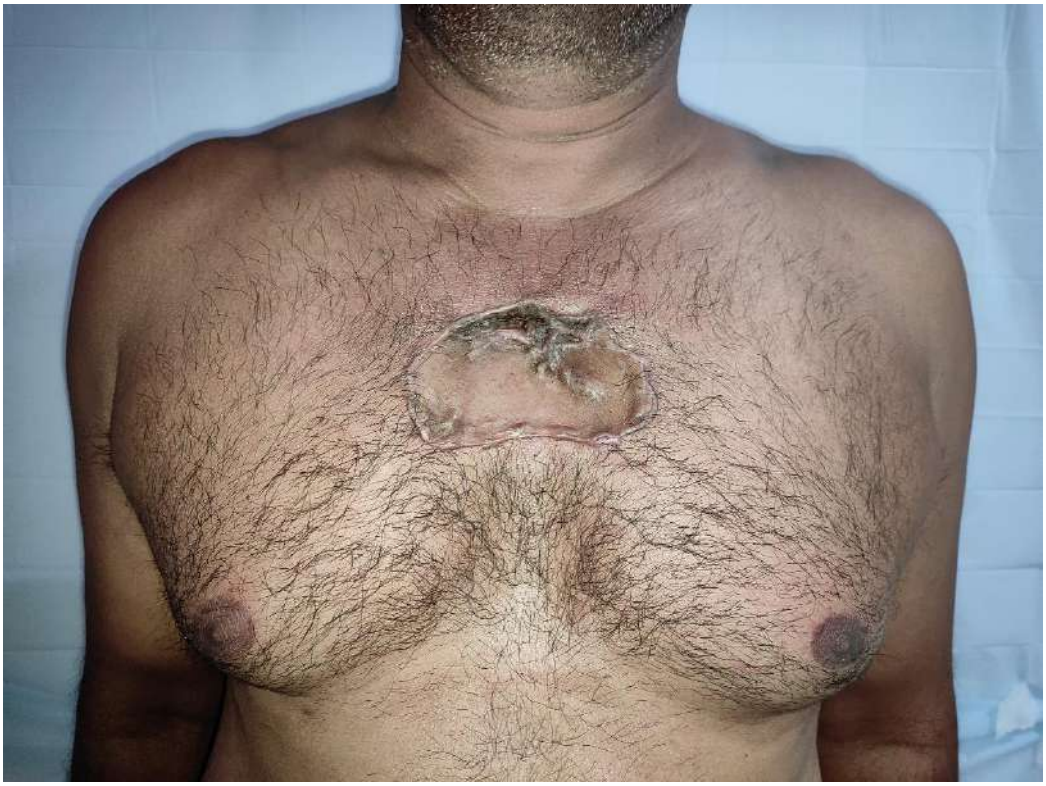


IMAGE 27: one-year post-op picture after STSG. Scar hypertrophy is seen at the graft loss site

Discussion

DISCUSSION

Most of our study patients belonged to the 20-30 and 30-40 age groups. The majority of our study patients were male patients (87%). In a study conducted by Cheruvu VPR et al., presternal keloids were found to be more common among males than females, with a male-to-female ratio of 2.35:1. One of the possible explanations for this is the presence of thick chest hair in males, which makes them more prone to folliculitis, which can lead to keloid genesis in the presternal region. They have also reported that the PSI chest hair pattern was mostly present in male patients presenting with presternal keloids [54]. According to the existing literature, there is a two- to 19-fold higher incidence of keloids in dark-skinned populations than in lighter-skinned populations. [54], [74].

As far as the treatment history was concerned, there were four patients with a history of surgical excision of the presternal keloid. About 11 patients had no history of intralesional steroid injections, whereas seven patients had more than five doses of intralesional triamcinolone injections previously. This shows that presternal keloids are a problematic condition wherein multiple treatments are used, and recurrence after treatments is common.

Keloids are pathological scars that can present with pain, itching, ulcers, and skin infections [75]. The incidence of keloids is affected by various local, systemic, and genetic factors. In our study, 15 patients (48.4%) have itching as their main complaint, and seven patients (22.6%) have pus discharge from the presternal keloid.

Our study used the POSAS scale for pre-op and post-op scoring. In a study by Nicholas et al., it was found that for the assessment of keloid scars, the Patient and Observer Scar Assessment Scale (POSAS) is associated with high internal consistency and “almost perfect” inter-observer reliability. It is more comprehensive than the Vancouver Scar Scale, which had lower internal consistency and interobserver reliability by comparison [76]. They

also stated that any tool that forms a part of the routine clinical assessment should be feasible for use in a busy outpatient clinic setting. In their study, given initial training and some practice, it was also found that the Patient and Observer Scar Assessment Scale was quick and easy to use [76]. Therefore, we have used POSAS in our study pre-operatively and one-year post-operatively. Both the scores were compared to assess the benefit of our intervention.

In our study, we found that 28 out of 31 patients had improvement in scores of both patient and observer POSAS scales. The patient scale's components, like pain, itching, color, stiffness, thickness, and irregularities, showed statistically significant improvement at one year compared to the preoperative values. All the components like vascularity, pigmentation, thickness, relief, surface area and pliability in the observer scale showed statistically significant improvement at one year compared to the preoperative values. In our study, three patients had worsened POSAS patient and observer scores when assessed after one year. They reported scar widening, especially at the flap donor site suture line, which was not relieved with adjuvant treatment therapies like intralesional triamcinolone injections and silicone gel.

All keloids showed greatly elevated levels of pro-α1(I) type I collagen mRNA in the dermis. Postsurgical wounds injected with triamcinolone after removal of the keloid expressed decreased pro-α1(I) collagen transcripts, compared with skin not treated with triamcinolone. The collagen bundles were also thinner and less dense in the triamcinolone-treated skin. Immediately triamcinolone injection after keloid excision elicits downregulation of the type I collagen gene expression. This suggests that prevention of recurrent keloid growth is possible if surgical excision is accompanied by immediate triamcinolone injection into the wound bed and that wound healing is not apparently compromised by inhibiting type I collagen gene expression. [77]

In our study, all patients received triamcinolone injections (40mg/ml) over the edges of the defect after the excision of the presternal keloids. The same was also given at the donor site of the local flaps before closure. Although conservative therapy has been recommended as the first-line treatment for keloids, surgical excision should be considered, especially in those with a poor response to conservative treatments. One of the critical elements of surgery is to reduce the wound tension, which has been considered a dominant factor in keloidogenesis.

A small-sized presternal keloid can be excised and the wound closed primarily. In our study, primary closure was preferred in patients with keloids of 1-4 cm2, i.e., with dimensions of 1-2 cm both horizontally and vertically. Overall, patient opinion and POSAS scores are statistically significant with p value < 0.001, showing improved scar quality and symptomatic relief at one year postoperatively.

In a study by Yoon et al., although there has been a success report, skin graft is inferior to flaps for two reasons. First, the expansion capability of a skin graft is not so good compared with a flap, sometimes even causing circular keloid recurrence from the incision. Besides, skin grafts have other disadvantages, such as contour deformity, color, and texture mismatch [78]. It has been found that the main problem associated with skin grafting is the recurrence of the keloid at the margins of the skin graft [79]. The final outcome of the scar is often positively correlated with the experience of the operating surgeon, and the technique utilized, as well as the patients' active participation in their wound care [80].

In our study, five patients had defects resurfaced with split-thickness skin graft after excision of presternal keloid for varied indications, and we have identified some features of abnormal scarring in the margins of the skin graft, which responded to intralesional triamcinolone injections. Among them, one patient had partial graft loss due to hematoma, and

the rest patients had optimum graft uptake. All of these patients had complete resolution of symptoms like pus discharge, itching, and burning sensation. One-year postoperative Likert's scores of these patients show statistically significant improvement compared to scores before surgery. Overall patient opinion and POSAS scores were also statistically significant, p value ≤0.001.

Our observational study showed that the graft had color and contour mismatch, and a patch of skin with slightly hypertrophied margins was cosmetically questionable. The intermediate thickness graft has the advantage of lack of hair growth, subsequently preventing folliculitis, an attributed cause for keloidogenesis. The donor sites of the graft were medial and anterior aspects of the thigh in our study. Two patients had hypertrophy of the donor site, which was managed by compression garments and silicone gel massage.

In our study, 16 patients (48.4%) were operated by presternal keloid excision and reconstruction by flap coverage. Our study used different flaps the intercostal artery perforator (IMAP), keystone, V-Y advancement, rotational, and Limberg flap. Flap survival was 100% (16 out of 16) in our study without partial or complete necrosis complications. All the flaps were monitored clinically in the immediate postoperative period. Additionally, flap temperatures were also observed using an infrared imaging camera. Flap blood glucose was also used to confirm the viability of the flap immediately after the inset. The flap blood glucose value, which was nearly normal to the patient's blood glucose, was a sure sign of the viability of the flap.

When it is difficult to close the wound primarily, local flaps are the best option. Freestyle or pedicled propeller flaps based on the IMA (internal mammary artery) perforators and keystone perforator island flaps are the options that can be considered. Tissue expansion can also be considered for large lesions [26]. Free flaps have also been used successfully to

reconstruct the defects after the excision of presternal keloids [27]. After any form of surgical excision, adjuvant treatments should be used to prevent recurrences.

Five patients underwent reconstruction by propeller flaps. Four patients had the 2nd intercoastal artery perforator (IMAP) flap cover, and one had the 4^{th} intercoastal artery perforator flap cover. In IMAP flap reconstruction, one of the complications found at the donor site was wound dehiscence. It was seen in one patient, and the dehisced wound had to be sutured twice, and then it gradually healed, resulting in the scar widening. Others had mild hypertrophy of the scar at the superior border of the flap inset. The presumed reason can be the gravitational pull of the flaps in the downward direction, causing slightly increased tension at the superior border compared to the inferior border of the flap.

In a case series conducted by Yoon et al., the classic type IIA keystone flap was used. It is ideal for chest keloid reconstruction because the flap can distribute tension evenly around the incision line. Previous studies have demonstrated that the levels of post-flap tension at both the defect and donor sites were significantly decreased compared with the pre-flap tension at the defect site, which indicated that the keystone flap had certainly reduced wound tension. Furthermore, it is simple to design, has a high success rate, and does not need meticulous dissection under the microscope. [78].

In our study, one patient underwent reconstruction with a keystone flap in which though the patient had symptomatic relief, the scar was found to be aesthetically unappealing over the chest as it extended up to breast regions beyond the presternal region. Suppose folliculitis was considered as a causative factor for keloid. In that case, all the patients in our study who have had reconstruction by flaps are advised for laser hair removal as an adjunct treatment over the presternal region to prevent future risk of keloidogeneis over the flap.

Other local flaps like rotational flap, Limberg flap, and V-Y advancement flap were also used to reconstruct the defect after excision of presternal keloid in our study. Five patients underwent reconstruction by bilateral rotational flap, three by limberg flap and two by V-Y advancement flap. The Y-limb of the V-Y advancement flap showed hypertrophy with scar widening in one of the patients.

Insertion of a tissue expander allows for an increase in skin island dimensions. It assists in donor site closure, resulting in the shortest incision line after surgery compared with other local flaps. Although tissue expanders are commonly inserted into the chest wall for breast reconstruction, it requires two-stage operations with intervals of several months, which is inconvenient for the patients. In addition, the patients with ulcers/infections on the keloids are unsuitable for tissue expander insertion. A tissue expander could be reserved for the patients who expect the shortest incision scar, have enough time, and do not have ulcers or infections on their keloids.

Akaishi et al. reported in their study the probable mechanism of origin of keloids and hypertrophic scars from the dermis, which led to the speculation that a reduction of tension on the wound dermis may reduce the risk of post-surgery keloid and hypertrophic scar formation. Therefore, we used subcutaneous/fascial tensile reduction sutures, which placed the tension on the deep and superficial fascia layers; the wound edges may thus be joined naturally under very small tension. This suturing strategy results in smooth wound edges with minimal tension on the dermis. Their preliminary evidence suggests that the approach hindered the development of large scars [79], [81] .

In our study, tension suturing was avoided at the flap margins and donor sites for all the cases. All the patients were given adjuvant treatments upon choice of the patients after explaining the advantages, ease of use, and disadvantages of each modality. The adjunct

treatment modalities used in our study were intralesional triamcinolone injections (40mg/ml) into the suture lines, silicone gel massage over the suture line, and silicone sheet application over the flap margins. Two patients in our study were given adjuvant external beam radiotherapy, five cycles of 25 gy from postoperative day 3 to day 7.

In our study, there was no statistically significant difference in the results among the patients treated with different types of reconstruction after the excision of presternal keloids. Inter-group comparison of each modality in POSAS, overall patient and observer opinions yielded a p-value of >0.05, which is statistically insignificant. Each of these resurfacing options had its own advantages and disadvantages. But overall, the disease burden could be significantly reduced after reconstruction for one year in our study. Further disease course, the possibility of recurrence of symptoms and keloids over the long term could not be assessed and will require longer follow-up periods for proper evaluation.

The fate of any keloid has continuous episodes of inflammation and remission occurring cyclically, along with increasing size of the lesion towards the line of skin tension. Furthermore, it is complicated by the ingrowing hair, resulting in the formation of sinuses with pus discharge if infection sets in. So, in our study, with the excision of presternal keloid followed by reconstruction, this cyclical disease process could be broken, and symptomatic relief can be offered to the patient. By excision of the presternal keloids, we could halt the progression of presternal keloids into larger lesions, providing symptomatic relief to the patients and improving their quality of life.

Intralesional steroids over a large surface area of the keloids are a painful experience for patients even after the usage of topical anesthesia. In our study, the patients who underwent the excision of presternal keloids and reconstruction required fewer injections and a lesser quantity of medication.

Keloids are known for their propensity for multiple recurrences. In our study, recurrence was considered significant if, at the final follow-up of one year post-surgery, the lesion size was the same or greater than the original keloid or if the POSAS patient and observer scores were the same or worse than the pre-op scores. In our study, three patients' POSAS scores worsened, indicating a poor outcome post-surgery. The recurrence rate in our study was found to be 9.67%, which is nearly similar to the recurrence rates (10.9%) of the study conducted by Arima et al. [58]

Summary

Summary

- A prospective observational study was carried out on patients admitted with presternal keloids in the Department of Burns and Plastic Surgery at the All India Institute of Medical Sciences, Bhopal, over 21 months (from February 2023 to October 2024).
- The study aimed to assess the functional and aesthetic outcomes in patients who underwent treatment of presternal keloids by our protocol of surgical excision, reconstruction, and adjuvant treatments
- Thirty-one patients were included in this study, of which 27 were males and 4 were females.
- The method of reconstruction selected depends on factors like the size of the defect and the availability of donor areas.
- In our study, the defects after excision of the presternal keloids were reconstructed by primary closure, local flaps, and split-thickness skin grafting. We performed reconstruction with primary closure in 10 patients; local flaps were used for reconstruction in 16 patients, and split-thickness skin grafting was used for reconstruction in five patients.
- As far as complications are concerned, no patients in our study had partial or total flap necrosis. Wound dehiscence occurred at the donor site in one patient two weeks after surgery. In six patients, scar hypertrophy at both donor sites and around the margins of the reconstructed site was found at a one-month postoperative period. One patient in our study had hematoma formation and partial graft loss.
- We evaluated the scar quality before surgery and at a one-year postoperative period using the POSAS patient and observer scale. We observed that 90.3% of the patients had better POSAS scores, whereas three patients had worsened POSAS scores.

- No significant correlation was seen between the POSAS scores of patients reconstructed by different techniques.
- The patient's subjective aesthetic/ satisfaction score assessment was measured using the Likert scale. 29 patients had a Likert score of ≤2/5 preoperatively and ≥3/5 one year postoperatively. Only two patients had a Likert's score of 1/5 pre- and post-operatively.
- At the one-year follow-up period, only three patients presented with recurrence of the lesions with scar widening and size of the lesion more than in the pre-operative period. This accounts for a recurrence rate of 9.67 % in our study, which is comparable with other studies.

Limitations

LIMITATIONS OF THE STUDY

- The findings of our study are limited by a relatively smaller sample size. Further studies with larger sample sizes are required to confirm the findings.
- The follow-up period was kept as one year in our study, considering the logistics of the time available to complete the M.Ch. dissertation. Ideally, considering the natural history of the disease, longer follow-up periods of 3-5 years are required to accurately evaluate the outcomes with regard to the recurrence of the lesions.
- Through our study, we have tried to advocate surgical excision, compression, and an additional adjuvant therapy among triamcinolone injection, silicone gel sheet application, silicone gel massage, and radiotherapy as a treatment for presternal keloids for achieving satisfactory outcomes. The second adjuvant therapy was according to the patient's choice. This factor could have a bearing on the reliability of our results.

Conclusion

CONCLUSION

Presternal keloids are a common clinical problem, accounting for nearly half of all newly occurring keloids. Thick chest hair in males, a propensity for recurrent folliculitis, and acne trigger the development of these lesions on the anterior chest. The presence of skin tension in this area leads to further growth and development of these lesions. They can grow to significant sizes over time. They can act as a source of distress to the patient, causing recurrent symptoms such as itching, pain, burning, and discomfort. In some cases, multiple sinus tracts develop within these lesions, sometimes with ingrown hair; in these cases, there are symptoms such as purulent discharge, redness, pain, and swelling. Sometimes these lesions are associated with the development of ulceration and bleeding. In most of the cases, presternal keloids also lead to a cosmetic deformity.

It is evident from the literature that treatments such as intralesional injections of different agents, silicones, compression, and lasers lead to some improvement in the symptomatology of these patients but do not remove the lesion completely, and recurrences can occur frequently. Further, these treatments may not be suited for large-sized keloids. Hence, we are advocating surgical excision for presternal keloids through our study.

The treatment of presternal keloids is a frustrating experience for surgeons, as these have a marked propensity to recur after excision, the recurrence rate being as high as 45%. Numerous authors have reported experiences with surgical interventions for presternal keloids in the literature, with varying results. Although there is a high rate of recurrence after the excision of presternal keloid, the addition of adjuvant treatments can reduce the incidence of recurrence. To reduce the chances of recurrence, we are advocating the addition of two adjuvant treatments. This strategy has led to an acceptable recurrence rate in our study patients. Our treatment aims to reduce symptoms, scar burden and promote functional and cosmetic improvements.

With this approach, the overall scar burden is also greatly reduced. Moreover, with conservative treatments, it is not possible to address the sinus tracts and in-growing hair, which leads to recurrent infections and interferes with the quality of life of patients. In such cases, management by excision offers satisfactory results, as this removes all the sinus tracts and ingrown hair which otherwise is not possible with conservative treatments.

We have used a well-established and well-validated scale like POSAS to evaluate the effectiveness of our intervention, and we have found a significant improvement in the POSAS scores following the intervention. We were also able to demonstrate an improvement in the aesthesis by comparing the pre-operative and one-year post-operative Likert's scores. This supports that our protocol of surgical intervention followed by adjuvant therapies is a beneficial strategy in the management of presternal keloids. However, our findings need to be taken with caution due to the small sample size and a short period of follow-up. Further studies with larger sample sizes are needed to confirm the findings of our study and to ensure a better understanding of the optimal treatment of presternal keloids.

We have also realized during the course of our study that presternal keloids are distinct from keloids occurring elsewhere in many aspects. They also have a varied presentation with regard to morphology and symptomatology. Hence, a grading system that is specific for presternal keloids would greatly enhance the communication among the various researchers working on the treatment of these lesions and may lead to better outcomes.

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Annexures

ANNEXURE I

PATIENT PROFORMA/ CASE RECORD FORM

Serial no:

Date:

CR No.:

Name:

Age:

Sex:

Address:

Date of admission: Date of surgery:

Diagnosis: Date of discharge:

Chief complaints:

History of present illness:

Past history:

Treatment history:

Personal history:

Family history:

General physical examination:

Pulse rate-

Blood pressure-

Respiratory rate-

Temperature-

Pallor, icterus, clubbing, pedal Edema, cyanosis, lymph nodes-

Systemic Examination:

CVS:

Respiration:

Per abdomen:

CNS:

Local Examination:

Site-

Size-

Shape-

Number-

Discharge-

Tenderness-

Preoperative evaluation: 1) scar quality based on POSAS

2) aesthesis based on Likert's scale

Investigations:

Complete blood picture

Liver and kidney function tests

PT/INR

X-ray chest

ECG

Other relevant investigations

Follow-up findings:

2nd day

1. Flap vitality
2. Hematoma/ seroma/ discharge

10th to 14th day

1. Flap vitality
2. Local complications, if any, like-
    - Symptoms
    - Scar hypertrophy

are charted, both at donor and recipient sites.

TIMELINE	RECIPIENT SITE	DONOR SITE
1 MONTH		
2 MONTHS		
3 MONTHS		
5 MONTHS		
7 MONTHS		
9 MONTHS		
11 MONTHS		
1 YEAR		

One-year post-reconstruction:

1. Scar quality (POSAS)
2. Aesthesis (Likert's scale)
3. Recurrence

TIMELINE	POSAS	LIKERTS
Preoperatively		
Postoperatively one year		

Signature of candidate

Dr. B Pragna Reddy

Signature of supervisor

Dr. Ved Prakash Rao Cheruvu

ANNEXURE II

PATIENT INFORMATION SHEET

1. **STUDY TITLE:** A prospective observational study on the treatment of presternal keloids by excision and reconstruction.

2. **STUDY INVESTIGATORS:**

   Student: Dr B Pragna Reddy, Burns & Plastic Surgery AIIMS Bhopal

3. **Guide:** Dr Ved Prakash Rao Cheruvu, Burns & Plastic Surgery, AIIMS Bhopal

4. **Co- Guide/s**

   Dr Manal M Khan, Burns & Plastic Surgery, AIIMS Bhopal

   Dr Deepak Krishna, Burns & Plastic Surgery, AIIMS Bhopal

   Dr Gaurav Chaturvedi, Burns & Plastic Surgery, AIIMS Bhopal

   Dr Rahul Dubepuria, Burns & Plastic Surgery, AIIMS Bhopal

5. **Introduction**:

We are conducting a research study to evaluate the effectiveness of treating presternal keloids by excision followed by reconstruction in the Burns & Plastic Surgery Department AIIMS Bhopal. We would like to invite you to take part in this study. We will ask you to sign a consent form if you agree to participate voluntarily.

6. **Purpose of the study:**

Our research aims to study the demographic features of patients presenting with presternal keloids, the various forms of reconstruction used after the excision of presternal keloids, the

incidence of complications, the post-operative quality of the scar, and the incidence of recurrence in the follow-up period.

This will help us find the usefulness of the treatment method by excision and reconstruction of presternal keloids.

7. Taking part – what it involves:

a. Do I have to take part?

Participation in this research is entirely voluntary. A decision to not take part or withdraw at any time will not affect your rights or medical care.

b. What is expected of me if I take part?

If you participate, we will operate you for presternal keloid by excision followed by reconstruction of the defect.

c. How long will my part in the study last?

Your participation in the study will last for 21 months. Follow-up will be till 1 year after the operation.

d. Do I have to come for extra visits or undergo extra investigations for the study?

No extra investigations/visits other than those required in routine for your disease management.

e. What are the possible benefits of taking part?

Taking part will help you gain knowledge about outcomes of excision and reconstruction which may result in improvement of management/outcomes for you / patients like yourself suffering from presternal keloids

f. What are the possible disadvantages and risks of taking part?

Other than those encountered during routine surgical treatment, there are no major foreseeable disadvantages or risks because of the study. There may be a risk of loss of privacy and confidentiality of information collected, even though all possible measures will be taken to ensure safe data storage and access.

g. What happens to the information collected from me?

All information collected will be kept strictly confidential and not shared with anyone. Results from the study will be reported as group data and will not identify you in any way.

h. What if I change my mind regarding participation in the study?

You are entitled to change your mind and withdraw anytime during the study without any disadvantage or penalty.

i. Whom do I contact for more information or if I have further questions or concerns?

If you want any information or have questions or concerns, you can contact:

Dr. B. Pragna Reddy,
Senior Resident,
Department of BPS, AIIMS, Bhopal
(8885863909, surgeonpragna@gmail.com)

Dr. Shashank Purwar
Member Secretary,
Institute Ethics Committee – Student Research
(7773010099, ihecpgr@aiimsbhopal.edu.in)

ANNEXURE III

प्रतिभागी सूचना पत्र

1. अध्ययन शीर्षक: छांटना और पुनर्निर्माण द्वारा प्रीस्टर्नल केलोइड्स के उपचार पर एक संभावित पर्यवेक्षणीय अध्ययन।

2. अध्ययन अन्वेषक:

छात्र: डॉ. बी प्रज्ञा रेड्डी, बर्न्स एंड प्लास्टिक सर्जरी एम्स भोपाल

3. मार्गदर्शक: डॉ वेद प्रकाश राव चेरुवु, बर्न्स एंड प्लास्टिक सर्जरी, एम्स भोपाल

4. सह-गाइड / एस

डॉ. मनल एम खान, बर्न्स एंड प्लास्टिक सर्जरी, एम्स भोपाल

डॉ. दीपक कृष्णा, बर्न्स एंड प्लास्टिक सर्जरी, एम्स भोपाल

डॉ गौरव चतुर्वेदी, बर्न्स एंड प्लास्टिक सर्जरी, एम्स भोपाल

डॉ. राहुल दुबेपुरिया, बर्न्स एंड प्लास्टिक सर्जरी, एम्स भोपाल

5. परिचय:

हम एम्स भोपाल के बर्न्स एंड प्लास्टिक सर्जरी विभाग में प्रीस्टर्नल केलोइड्स के उपचार की प्रभावशीलता का मूल्यांकन करने के लिए एक शोध अध्ययन कर रहे हैं। हम आपको इस अध्ययन में भाग लेने के लिए आमंत्रित करना चाहते हैं। यदि आप स्वेच्छा से भाग लेने के लिए सहमत हैं, तो हम आपसे एक सहमति फॉर्म पर हस्ताक्षर करने के लिए कहेंगे।

6. अध्ययन का उद्देश्य:

हमारे शोध का उद्देश्य अध्ययन करना है: प्रीस्टर्नल केलोइड्स के साथ पेश होने वाले रोगियों की जनसांख्यिकीय विशेषताएं, प्रीस्टर्नल केलोइड्स के छांटने के बाद उपयोग किए जाने वाले पुनर्निर्माण के विभिन्न रूप, जटिलताओं की घटना और निशान की पोस्ट-ऑपरेटिव गुणवत्ता, घटना अनुवर्ती अवधि में

पुनरावृत्ति।यह हमें प्रीस्टर्नल केलोइड्स के छांटने और पुनर्निर्माण द्वारा उपचार पद्धति की उपयोगिता खोजने में मदद करेगा।

7. भाग लेना - इसमें क्या शामिल है:

a) क्या मुझे भाग लेना है?

इस शोध में भागीदारी पूरी तरह से स्वैच्छिक है। भाग न लेने या किसी भी समय वापस लेने का निर्णय किसी भी तरह से आपके अधिकारों या चिकित्सा देखभाल को प्रभावित नहीं करेगा।

b) यदि मैं भाग लेता हूँ तो मुझसे क्या अपेक्षा की जाती है?

यदि आप भाग लेते हैं, तो हम आपको प्रीस्टर्नल केलोइड के लिए ऑपरेशन करेंगे, जिसके बाद दोष का पुनर्निर्माण होगा।

c) अध्ययन में मेरा हिस्सा कितने समय तक चलेगा?

अध्ययन में आपकी भागीदारी 21 महीनों तक चलेगी। ऑपरेशन के 1 साल बाद तक फॉलोअप होगा।

d) क्या मुझे अध्ययन के लिए अतिरिक्त मुलाकातों या अतिरिक्त जांचों के लिए आना होगा?

आपके रोग प्रबंधन के लिए नियमित रूप से आवश्यक के अलावा कोई अतिरिक्त जांच/मुलाकात नहीं।

e) भाग लेने में संभावित लाभ क्या हैं?

भाग लेने से उच्छेदन और पुनर्निर्माण के परिणामों के बारे में ज्ञान प्राप्त करने में मदद मिलेगी जिसके परिणामस्वरूप प्रबंधन में सुधार हो सकता है / आपके लिए परिणाम / आप जैसे मरीज जो प्रीस्टर्नल केलोइड्स से पीड़ित हैं.

f) भाग लेने के संभावित नुकसान और जोखिम क्या हैं?

नियमित शल्य चिकित्सा उपचार के दौरान सामना किए जाने के अलावा, अध्ययन के कारण कोई प्रमुख अनुमानित नुकसान या जोखिम नहीं हैं। एकत्र की गई जानकारी की गोपनीयता और गोपनीयता के नुकसान का जोखिम हो सकता है, भले ही सुरक्षित डेटा भंडारण और पहुंच सुनिश्चित करने के लिए सभी संभव उपाय किए जाएंगे।

g) मुझसे एकत्र की गई जानकारी का क्या होता है?

एकत्र की गई सभी सूचनाओं को कड़ाई से गोपनीय रखा जाएगा और किसी के साथ साझा नहीं किया जाएगा। अध्ययन के परिणाम समूह डेटा के रूप में रिपोर्ट किए जाएंगे और किसी भी तरह से आपकी पहचान नहीं करेंगे।

h) क्या होगा यदि मैं अध्ययन में भाग लेने के संबंध में अपना विचार बदल दूं?

आप अपना विचार बदलने और अध्ययन के दौरान किसी भी समय बिना किसी नुकसान या दंड के वापस लेने के हकदार हैं।

i) अधिक जानकारी के लिए मैं किससे संपर्क करूँ या यदि मेरे कोई और प्रश्न या चिंताएँ हैं?

यदि आप कोई जानकारी चाहते हैं या कोई प्रश्न या चिंता है, तो आप संपर्क कर सकते हैं:

डॉ. बी प्रज्ञा रेड्डी
सीनियर रेजिडेंट,
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डॉ. शशांक पुरवार
सदस्य सचिव,
संस्थान आचार समिति - छात्र अनुसंधान
(7773010099, ihecpgr@aiimsbhopal.edu.in)

ANNEXURE IV

प्रतिभागी सूचना सहमति प्रपत्र

[PARTICIPANT INFORMED CONSENT FORM (PICF)]

अध्ययन के लिए प्रतिभागी का पहचान नंबर / Participant Identification Number for Study: …….. …… अनुसंधान का शीर्षक / Title of Project : **A prospective observational study on the treatment of presternal keloids by excision and reconstruction. / छांटना और पुनर्निर्माण द्वारा प्रीस्टर्नल केलोइड्स के उपचार पर एक संभावित पर्यवेक्षणीय अध्ययन।**

छात्र शोधकर्ता का नाम / Name of Student Investigator: Dr B. Pragna Reddy/ डॉ. बी प्रज्ञा रेड्डी

शोध मार्गदर्शक का नाम / Name of Thesis Guide : Dr Ved Prakash Rao Cheruvu/ डॉ वेद प्रकाश राव चेरुवु

मैंने संस्करण संख्या II…… दिनांक 20-08-2022 के सूचना पत्रक में दिए गए सभी तथ्यों को सावधानीपूर्वक पढ़ लिया है/ मुझे अपनी भाषा में स्पष्ट रूप से विस्तारपूर्वक समझा दिया गया है, और मैंने तथ्यों को पूर्णतः समझ लिया है। मैं पुष्टि करता/ करती हूँ, कि मुझे सवाल पूछने के अवसर प्रदान किए गए। The contents of the information sheet version II dated 16th January 2023 that was provided have been read carefully by me / explained in detail to me, in a language that I comprehend, and I have fully understood the contents. I confirm that I have had the opportunity to ask questions.

मुझे इस अध्ययन की प्रकृति एवं उद्देश्य और इसके संभावित जोखिमों / लाभों तथा अध्ययन की अनुमानित अवधि एवं अन्य प्रासंगिक जानकारी के बारे में विस्तारपूर्वक समझा दिया गया है। मुझे पता है कि इस

अध्ययन में मेरी भागीदारी स्वैच्छिक है तथा मैं इस अध्ययन से किसी भी समय बिना कोई कारण बताए, अपना नाम वापस लेने के लिए स्वतंत्र हूं और नाम वापस लेने पर मेरी चिकित्सा देखभाल या कानूनी अधिकारों पर कोई प्रभाव नहीं पड़ेगा। The nature and purpose of the study and its potential risks/benefits and expected duration of the study, and other relevant details of the study have been explained to me in detail. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal right being affected.

मैं समझता/समझती हूं कि इस अनुसंधान में मेरी भागीदारी से मेरे बारे में एकत्र की गई जानकारी और मेरे चिकित्सीय दस्तावेजों के किसी भी भाग को एम्स के जिम्मेदार व्यक्तियों द्वारा ही देखा जाएगा। मैं इन व्यक्तियों को मेरे रिकॉर्ड प्राप्त करने की अनुमति प्रदान करता/ करती हूँ। I understand that the information collected about me from my participation in this research and sections of any of my medical notes may be looked at by responsible individuals from AIIMS. I give permission for these individuals to have access to my records.

मैं उक्त अध्ययन में भाग लेने के लिए सहमत हूं। I agree to take part in the above study.

_____

(प्रतिभागी के हस्ताक्षर / बांए अंगूठे का निशान) (Signature / Left Thumb Impression)

दिनांक/Date……स्थान/Place …….....

प्रतिभागी का नाम/Name of the participant …….....

पिता/पति/पत्नी का नाम /Son/Daughter/Spouse of…….

डाक का पूरा पता /Complete Postal Address ……....

अगर अशिक्षित हो/ If illiterate,

सूचना पत्र को प्रतिभागी को पढ़ा और समझाया गया है, और प्रश्न पूछने का अवसर दिया गया है। मैं पुष्टि करता हूं कि व्यक्ति ने स्वतंत्र रूप से सहमति दी है।

The information sheet has been read and explained to the participant, and given the opportunity to ask questions. I confirm that the individual has given consent freely.

कानूनी रूप से स्वीकार्य प्रतिनिधि अथवा निष्पक्ष गवाह के हस्ताक्षर

Signature of Legally Acceptable Representative or impartial witness: _____

दिनांक / Date:

एलएआर अथवा निष्पक्ष गवाह का नाम / Name of LAR or impartial witness:

पता/Address:

प्रमाणित किया जाता है कि उक्त सहमति मेरी उपस्थिति में प्राप्त की गई ।

This is to certify that the above consent has been obtained in my presence.

_____

छात्र शोधकर्ता के हस्ताक्षर दिनांक…….स्थान……

Signature of the Student Investigator Date ……Place …….

कृपया ध्यान दें: सहमति प्रपत्र तीन प्रतियों में (1) रोगी के लिए, (2) शोधकर्ता, (3) संस्थान के लिए तैयार करें ।

Please note: Three copies should be made, for (1) Patient, (2) Researcher, (3) Institution

ANNEXURE V

POSAS Observer scale

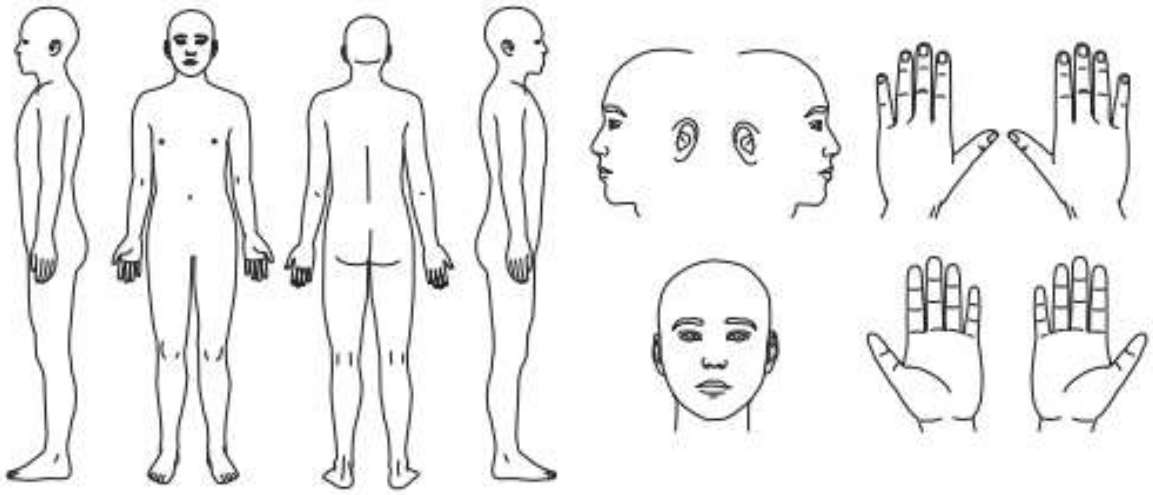
The Patient and Observer Scar Assessment Scale v2.0 / EN

Date of examination: _____ **Name of patient:** _____

Observer: _____ _____

Location: _____ **Date of birth:** _____

Research / study: _____ **Identification number:** _____



PARAMETER	1 = normal skin	2	3	4	5	6	7	8	9	worst scar imaginable = 10	CATEGORY
VASCULARITY	○	○	○	○	○	○	○	○	○	○	PALE | PINK | RED | PURPLE | MIX
PIGMENTATION	○	○	○	○	○	○	○	○	○	○	HYPO | HYPER | MIX
THICKNESS	○	○	○	○	○	○	○	○	○	○	THICKER | THINNER
RELIEF	○	○	○	○	○	○	○	○	○	○	MORE | LESS | MIX
PLIABILITY	○	○	○	○	○	○	○	○	○	○	SUPPLE | STIFF | MIX
SURFACE AREA	○	○	○	○	○	○	○	○	○	○	EXPANSION | CONTRACTION | MIX
OVERALL OPINION	○	○	○	○	○	○	○	○	○	○	

Explanation

The observer scale of the POSAS consists of six items (vascularity, pigmentation, thickness, relief, pliability and surface area).
All items are scored on a scale ranging from 1 ('like normal skin') to 10 ('worst scar imaginable').
The sum of the six items results in a total score of the POSAS observer scale. Categories boxes are added for each item. Furthermore, an overall opinion is scored on a scale ranging from 1 to 10.
All parameters should preferably be compared to normal skin on a comparable anatomic location.

Explanatory notes on the items:

- **VASCULARITY** Presence of vessels in scar tissue assessed by the amount of redness, tested by the amount of blood return after blanching with a piece of Plexiglas
- **PIGMENTATION** Brownish coloration of the scar by pigment (melanin); apply Plexiglas to the skin with moderate pressure to eliminate the effect of vascularity
- **THICKNESS** Average distance between the subcutical-dermal border and the epidermal surface of the scar
- **RELIEF** The extent to which surface irregularities are present (preferably compared with adjacent normal skin)
- **PLIABILITY** Suppleness of the scar tested by wrinkling the scar between the thumb and index finger
- **SURFACE AREA** Surface area of the scar in relation to the original wound area

POSAS Patient scale

The Patient and Observer Scar Assessment Scale v2.0 / EN

Date of examination:

Name of patient:

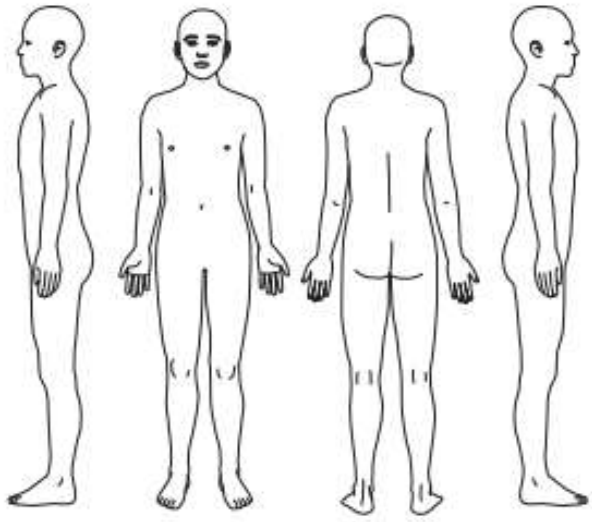
Observer:

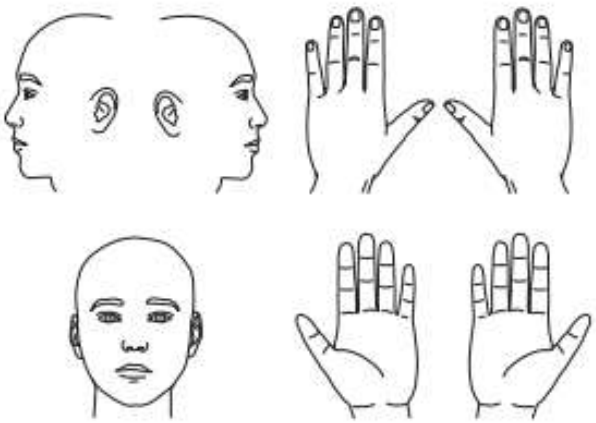
Location:

Date of birth:

Research / study:

Identification number:





	1 = no, not at all									yes, very much = 10
	1	2	3	4	5	6	7	8	9	10
HAS THE SCAR BEEN PAINFUL THE PAST FEW WEEKS?	○	○	○	○	○	○	○	○	○	○
HAS THE SCAR BEEN ITCHING THE PAST FEW WEEKS?	○	○	○	○	○	○	○	○	○	○

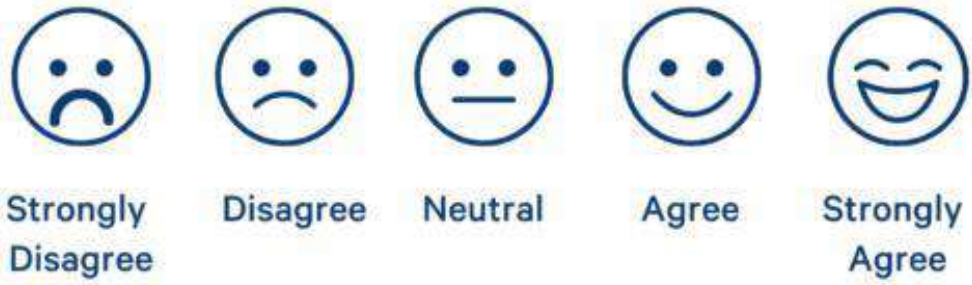
	1 = no, as normal skin									yes, very different = 10
	1	2	3	4	5	6	7	8	9	10
IS THE SCAR COLOR DIFFERENT FROM THE COLOR OF YOUR NORMAL SKIN AT PRESENT?	○	○	○	○	○	○	○	○	○	○
IS THE STIFFNESS OF THE SCAR DIFFERENT FROM YOUR NORMAL SKIN AT PRESENT?	○	○	○	○	○	○	○	○	○	○
IS THE THICKNESS OF THE SCAR DIFFERENT FROM YOUR NORMAL SKIN AT PRESENT?	○	○	○	○	○	○	○	○	○	○
IS THE SCAR MORE IRREGULAR THAN YOUR NORMAL SKIN AT PRESENT?	○	○	○	○	○	○	○	○	○	○

	1 = as normal skin									very different = 10
	1	2	3	4	5	6	7	8	9	10
WHAT IS YOUR OVERALL OPINION OF THE SCAR COMPARED TO NORMAL SKIN?	○	○	○	○	○	○	○	○	○	○

ANNEXURE- VI

LIKERT'S SCALE

Name: _____ Date: _____



ANNEXURE VII

POSAS LICENSE

POSAS <info@posas.nl> 14 Jan 2023, 14:17

to me

Dear Dr B Pragna Reddy, Thank you for your interest in the POSAS. We hereby grant you permission to use the POSAS free of charge for non-commercial purposes. Please find attached the license agreement. We advise you to download the license agreement for your own administration. A summary of the information you have submitted is provided below. Please carefully review this information and notify us if you have any questions or concerns.

Download your POSAS 3.0 directly:

POSAS 3.0 contains 4 questionnaires per language. The Observer and Patient scales, and the Generic and Linear scar versions.

- Download POSAS 3.0 English (ZIP)
- Download POSAS 3.0 Dutch (ZIP)

Download the POSAS 2.0:

- Download POSAS 2.0 English (PDF)
- Download POSAS 2.0 Dutch (PDF)
- Download POSAS 2.0 German (PDF)
- Download POSAS 2.0 Spanish (PDF)
- Download POSAS 2.0 French (PDF)
- Download POSAS 2.0 Czech (PDF)
- Download POSAS 2.0 Bulgarian-Observer Scale (PDF)
- Download POSAS 2.0 Bulgarian-Patient Scale (PDF)
- Download POSAS 2.0 Swedish (PDF)
- Download POSAS 2.0 Slovak (PDF)
- Download POSAS 2.0 Romanian (PDF)
- Download POSAS 2.0 Japanese-Patient Scale (PDF)
- Download POSAS 2.0 Norwegian (PDF)
- Download POSAS 2.0 Japanese-Observer Scale (PDF)
- Download POSAS 2.0 Italian (PDF)
- Download POSAS 2.0 Hebrew (PDF)

We hope that the POSAS will be a valuable contribution to your efforts to achieve your clinical and research goals. Kind regards, The POSAS team

License

- Type of license: **Non-commercial license**
- Language(s): **English POSAS 3.0**

Licensee information

- Name: **Dr B Pragna Reddy**
- E-mail: surgeonpragna@gmail.com
- Organisation: **Aiims Bhopal, Burns, and plastic surgery**

Total licensing cost: 0 euro

SUMMARY:

Purpose of use
Research
Objective of the measurement
A prospective observational study on the treatment of presternal keloid by excision and reconstruction
Name contact person
Dr B Pragna Reddy
Email
surgeonpragna@gmail.com
Name Company or hospital
Aiims bhopal
Department
Burns and plastic surgery
Consent
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Van de Kar, AL, Corion, LU, Smeulders, MJ, Draaijers, LJ, van der Horst, CM, van Zuijlen, PP. Reliable and feasible evaluation of linear scars by the Patient and Observer Scar Assessment Scale. Plast Reconstr Surg. 2005; 116:514-522.

Order

Product	Qty	Unit Price	Price
Non-commercial license			
Select your language(s) for POSAS 2.0 or 3.0: English POSAS 3.	1	0,00 €	0,00 €
		Sub Total	0,00 €
		Total	0,00 €

ANNEXURE VIII

Undertaking

This is to certify that

1. The Hindi-translated versions of the Patient Information Sheet (PIS) and Informed Consent Forms (ICF) are true to the meaning of the English versions. They have been translated and back-translated to check for validity.

2. Questionnaire "The Patient and Observer Scar Assessment Scale v2.0" English language (POSAS) used in the study is freely available in the public domain. The permission to use the scale has been obtained from the copyright holder (attached in Annexure)

3. The questionnaire "Likert's scale" is freely available in the public domain; no special permission is required to use this scale.

Dr. B Pragna Reddy

ANNEXURE IX

MASTER CHART

Case no.	AGE	SEX	SIZE OF PRESTERNAL KELOID (MAXIMUM HORIZONTAL SIZE IN CM)	SIZE OF PRESTERNAL KELOID (MAXIMUM VERTICAL SIZE IN CM)	TREATMENT HISTORY (NO. OF DOSES OF INTRALESIONAL TRIAMCINOLONE INJECTION)	HISTORY OF SURGICAL EXCISION	ASSOCIATED SYMPTOMS (ITCHING, PUS DISCHARGE, BURNING SENSATION)
1	60	F	5	3	0	NO	Itching, burning sensation
2	46	M	5	3	>5	NO	Itching, pus discharge
3	46	M	4	1.5	>5	NO	Itching, pus discharge
4	40	M	6	3	>5	NO	Itching
5	55	M	14	5	>5	NO	Itching, pus discharge
4	30	M	3.5	1.5	0	NO	Itching, burning sensation
7	29	F	3	2	0	NO	Itching
8	55	M	4	3	0	NO	Itching, burning sensation
9	39	M	3	1	5	NO	Itching
10	31	M	2	2	0	NO	Itching
11	35	M	7	2	4	NO	Itching, pus discharge
12	35	M	5	2	4	NO	Itching, pus discharge
13	35	M	4	2	4	NO	Itching
14	42	M	4	5	>5	YES (3 YEARS AGO)	Pus discharge
15	24	M	5	3	4	NO	Itching, burning sensation
16	48	M	10	3	3	NO	Itching, pus discharge
17	48	M	2	1	3	NO	Itching, pus discharge
18	37	M	4	3	2	NO	Itching
19	30	F	4	2	0	NO	Itching
20	24	F	3	2	0	YES (1 YEAR AGO)	Itching
21	34	M	6	3	>5	NO	Itching, burning sensation
22	34	M	2	2	>5	NO	Itching, burning sensation
23	48	M	1	1	3	NO	Itching
24	48	M	3	1	3	NO	Itching
25	48	M	2	1	3	NO	Itching
26	29	M	4	2	4	YES	Itching, burning sensation
27	29	M	1	1	4	YES	Itching, burning sensation
28	23	M	4	3	0	NO	Itching
29	23	M	2	1	0	NO	Itching
30	23	M	1	1	0	NO	Itching
31	33	M	1	1	0	NO	Itching

Case no.	DEFECT SIZE AFTER EXCISION (MAXIMUM HORIZONTAL SIZE IN CM)	DEFECT SIZE AFTER EXCISION (MAXIMUM VERTICAL SIZE IN CM)	DEFECT RESURFACED BY	POST OP COMPICATIONS	ADJUVANT THERAPY POST-OP
1	7.7	4	left 4th IMAP propeller flap	scar hypertrophy	6 doses triamcinolone
2	5	4	left 2nd IMAP propeller flap	nil	5 doses triamcinolone
3	4	4	left 2nd IMAP propeller flap	nil	5 doses triamcinolone
4	7	4	left 2nd IMAP propeller flap	scar hypertrophy	4 doses triamcinolone
5	16.5	5	STSG	hematoma	Silicone gel massage
4	4	2	Limberg flap	scar hypertrophy	Silicone gel massage
7	4	5	B/L V-Y advancement flap	nil	silicone sheet
8	4.5	3.5	excision + STSG	nil	5 cycles of radiation
9	4	2	excision + STSG	nil	silicone sheet
10	3	4	Limberg flap	nil	5 cycles of radiation
11	9	5	left 2nd IMAP propeller flap	scar hypertrophy	Silicone sheet
12	6	2.5	primary closure	scar hypertrophy	Silicone sheet
13	5	3	primary closure	scar hypertrophy	Silicone sheet
14	8	7	STSG	NIL	2 doses triamcinolone
15	6	4	B/L V-Y advancement flap	nil	Silicone gel massage
16	13	4.5	keystone flap	nil	Silicone gel massage
17	3	1.5	primary closure	nil	Silicone gel massage
18	5	4	excision + INTEGRA+ STSG	nil	Silicone gel massage
19	4	3	primary closure	nil	Silicone gel massage
20	4	3	Limberg flap	wound dehiscence	silicone sheet
21	7	4	B/L rotational flap	nil	silicone sheet
22	3.5	3	B/L rotational flap	nil	silicone sheet
23	1.5	1.5	primary closure	nil	2 doses triamcinolone
24	3.5	2	primary closure	nil	2 doses triamcinolone
25	3	1.5	primary closure	nil	2 doses triamcinolone
26	5	2.5	B/L rotational flap	nil	Silicone gel massage
27	2	2	B/L rotational flap	nil	Silicone gel massage
28	5	3.5	rotational flap	nil	Silicone gel massage
29	3	2.5	primary closure	nil	Silicone gel massage
30	2	2	primary closure	nil	Silicone gel massage
31	2	2	primary closure	nil	Silicone gel massage

Case no.	LIKERTS PREOP	LIKERTS 1 YEAR POST-OP	PRE-OP OVERALL PATIENT OPINION	1 YEAR POST-OP OVERALL PATIENT OPINION	PRE-OP OVERALL OBSERVER OPINION	1 YEAR POST-OP OVERALL OBSERVER OPINION	PRE-OP POSAS PATIENT SCORE	1 YEAR POST-OP POSAS PATIENT SCORE
1	2	3	8	4	7	4	30	14
2	2	3	8	5	7	3	31	16
3	1	4	8	2	8	2	26	13
4	1	3	9	4	8	4	28	12
5	2	3	7	3	8	4	42	18
4	2	4	6	2	5	3	17	9
7	1	1	6	3	5	5	34	14
8	2	3	6	4	6	4	28	15
9	1	3	5	4	5	5	30	16
10	2	3	5	3	4	3	30	14
11	1	3	7	4	8	4	38	16
12	1	3	9	3	9	3	41	12
13	1	4	9	4	9	4	38	13
14	1	3	9	4	9	4	32	12
15	2	4	5	3	5	4	22	11
16	2	3	8	3	8	4	30	13
17	2	4	5	4	6	4	12	10
18	2	2	5	2	4	2	7	9
19	1	3	5	3	5	2	26	9
20	1	1	5	1	5	2	7	9
21	1	4	6	4	5	3	26	13
22	1	4	7	3	5	4	36	12
23	2	1	6	5	4	6	16	24
24	2	4	8	3	7	2	22	7
25	2	4	2	1	2	1	8	7
26	1	3	6	3	6	3	51	12
27	1	4	6	2	5	2	31	7
28	1	3	6	3	6	2	27	10
29	1	4	4	2	4	2	18	6
30	2	3	4	2	4	2	15	11
31	2	3	6	3	5	3	32	11

Case no.	PRE-OP POSAS OBSERVER SCORE	1 YEAR POST-OP POSAS OBSERVER SCORE	PAIN	1YEAR POST-OP PAIN	ITCHING	1YEAR POST-OP ITCHING	COLOUR	1 YEAR POST-OP COLOUR
1	37	15	2	2	5	3	4	1
2	33	17	2	1	6	2	7	3
3	22	14	2	1	6	2	4	3
4	24	14	2	1	7	2	3	2
5	36	14	6	2	9	3	5	3
4	23	12	1	1	3	2	6	1
7	28	23	4	1	6	2	6	2
8	28	16	4	2	6	3	4	2
9	28	20	4	1	7	3	4	3
10	25	12	5	1	6	2	4	2
11	38	15	5	1	8	3	5	1
12	41	12	6	1	9	3	4	1
13	40	12	6	1	8	4	5	2
14	35	13	4	1	6	2	5	2
15	21	11	3	1	6	1	2	2
16	39	17	4	1	7	2	3	2
17	11	12	1	1	1	2	1	1
18	10	11	1	1	1	1	1	1
19	18	10	2	1	5	1	5	1
20	8	9	1	1	1	1	1	1
21	35	18	3	1	5	2	2	2
22	36	15	4	1	7	2	5	2
23	19	26	1	1	2	2	3	4
24	25	7	1	1	4	1	3	1
25	10	7	1	1	2	1	1	1
26	40	11	6	1	8	2	6	2
27	23	9	6	1	7	1	5	1
28	31	10	3	1	7	2	3	1
29	20	7	1	1	4	1	3	1
30	19	10	2	1	3	2	2	1
31	30	12	3	1	7	2	6	2

Case no.	STIFFNESS	1YEAR POST-OP STIFFNESS	THICKNESS	1YEAR POST-OP THICKNESS	IRREGULARITY	1YEAR POST-OP IRREGULARITY	VASCULARITY	1YEAR POST-OP VASCULARITY
1	5	2	7	3	7	3	4	2
2	5	3	4	3	7	4	3	2
3	4	2	5	2	5	3	2	2
4	4	2	4	2	8	3	2	1
5	6	3	7	3	9	4	4	2
4	2	2	3	2	2	1	4	2
7	6	2	7	2	5	5	4	4
8	4	2	5	3	5	3	2	2
9	5	3	5	2	5	4	3	1
10	5	2	6	3	4	4	3	2
11	5	2	6	3	9	3	5	2
12	7	2	7	2	8	3	6	2
13	6	2	6	2	7	2	6	2
14	6	2	4	3	7	2	4	2
15	2	2	3	2	6	3	2	1
16	4	3	5	2	7	3	5	2
17	3	2	3	2	3	2	1	1
18	1	3	2	2	1	1	1	2
19	5	2	5	2	4	2	3	1
20	1	3	2	2	1	1	1	2
21	5	2	6	3	5	3	4	2
22	7	2	6	2	7	3	5	3
23	5	6	5	3	4	8	2	2
24	5	2	3	1	6	1	3	1
25	1	2	2	1	1	1	2	1
26	6	2	6	2	7	3	6	1
27	4	2	6	1	3	1	3	2
28	5	2	4	2	5	2	4	1
29	4	1	3	1	3	1	2	1
30	3	2	2	2	3	3	2	1
31	5	2	6	2	5	2	3	1

Case no.	Pigmentation	1YEAR POST -OP Pigmentation	Thickness	1YEAR POST -OP Thickness	Relief	1YEAR POST -OP Relief	Pliability	1YEAR POST - OP Pliability	Surface area	1YEAR POST - OP Surface area
1	5	2	7	2	6	3	7	3	8	3
2	6	3	5	2	6	3	6	3	7	4
3	3	3	2	2	5	2	4	2	6	3
4	3	4	3	2	5	3	5	2	6	2
5	4	2	5	2	8	2	7	3	8	3
4	6	2	3	2	2	2	4	2	4	2
7	6	2	4	2	4	4	5	4	5	7
8	3	2	4	2	6	4	6	3	7	3
9	3	2	4	3	5	4	6	4	7	6
10	5	2	4	2	5	2	4	2	4	2
11	4	1	6	3	8	3	7	3	8	3
12	5	1	7	2	7	2	8	2	8	3
13	5	1	7	2	7	2	7	2	8	3
14	5	2	5	2	6	2	7	3	8	2
15	2	1	2	2	5	2	4	2	6	3
16	5	2	7	2	8	4	6	3	8	4
17	1	1	2	2	2	2	3	2	2	4
18	1	1	2	3	2	1	2	2	2	2
19	3	1	3	2	3	2	2	2	4	2
20	1	1	2	2	1	1	1	2	2	1
21	5	2	6	3	6	4	7	3	7	4
22	5	2	6	2	7	2	6	2	7	4
23	3	3	5	3	3	6	2	4	4	8
24	12	1	4	1	6	1	2	1	8	2
25	2	1	2	1	1	1	2	1	1	2
26	5	2	7	2	7	2	8	2	7	2
27	4	1	4	1	3	1	5	2	4	2
28	4	1	5	2	5	2	6	2	7	2
29	4	1	4	1	3	1	4	2	3	1
30	2	1	3	2	4	2	3	2	5	2
31	5	2	5	2	4	2	7	3	6	2